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**Chemical Reporting and Record-Keeping
Authorities Under 15
Environmental and Consumer Acts**

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Toxic Substances

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Chemical Reporting and Record-Keeping Authorities under 15 Environmental and Consumer Acts

TSCA

RCRA

FIFRA

CAA

FWPCA

SDWA

FD&CA

OSHA

FMS&HA

CPSA

FHSA

FFA

PPPA

HMTA

RSA

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16. ABSTRACT △ This report is an indexed compendium of authorities to gather and disseminate information which occur in the listed acts. It contains a subject index to facilitate searching these acts for specific types of authorities. It also contains an abridged text of the acts, edited for clarity and brevity.					
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**CHEMICAL REPORTING AND RECORD-KEEPING
AUTHORITIES UNDER 15 ENVIRONMENTAL
AND CONSUMER ACTS**

**Prepared by
Chemical Information Division
Office of Program Integration and Information
Office of Toxic Substances
Environmental Protection Agency**

December 15, 1978



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF TOXIC SUBSTANCES

FOREWORD

Effective integration of Federal information-gathering efforts requires that staff and responsible program officers be aware of the activities of other Federal agencies. Because there was no available source describing the statutory authorities under which various agencies gather data, the Office of Program Integration and Information has developed this compendium which abstracts information-gathering authorities under 15 environmental and consumer acts. Initially it was intended to be an internal reference document for use by the staff of the Office of Toxic Substances. However, during the course of wide interagency review several other programs expressed an interest in having a copy of the final compendium. Accordingly, we have arranged for its publication as an EPA report.

This compendium was developed to:

1. determine what record-keeping and reporting authorities exist among various Federal statutes;
2. aid in avoiding duplicative record-keeping and reporting requirements; and
3. ensure that the most efficient and effective authority is used to obtain the desired information.

In this final form, the compendium includes an introduction explaining the rationale, organization, and use of the document; an annotated index; and an edited version of the texts of the acts. It was designed to allow the user to rapidly and conveniently survey these fifteen acts for various types of information-gathering authorities.

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Toxic Substances Control Act
Resource Conservation and Recovery Act
Federal Insecticide, Fungicide and Rodenticide Act
Clean Air Act
Federal Water Pollution Control Act
Safe Drinking Water Act
Federal Food, Drug and Cosmetic Act
Occupational Safety and Health Act
Federal Mine Safety and Health Act
Consumer Product Safety Act
Federal Hazardous Substances Act
Flammable Fabrics Act
Poison Prevention Packaging Act
Hazardous Materials Transportation Act
Federal Railroad Safety Act of 1970

INTRODUCTION

The Office of Program Integration and Information, of the Office of Toxic Substances, Environmental Protection Agency, has primary responsibility for coordinating the reporting and record-keeping activities under the Toxic Substances Control Act (TSCA) with those undertaken under other authorities. Section 10 requires development of systems to facilitate exchange and dissemination of toxic substances information gathered by Federal agencies. Subsection 9(d) charges the Administrator with "achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements", and subsection 8(a) reads in part, "To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative". Currently the Office of Program Integration and Information is involved in numerous interagency efforts to coordinate TSCA information-gathering with other Federal programs. This compendium was developed to serve as a quick reference to the types of reporting and record-keeping authorities contained in pertinent Federal, environmental and consumer legislation.

Two caveats are in order. First, the language of these acts has been freely edited in the interest of brevity and clarity. Very little of the text has been left unchanged from the original legislative language. For this reason, recourse to a true and complete copy of the act is recommended in all instances.

Secondly, much of the statutory language has been omitted entirely. In most cases, much of an act was not relevant to information-gathering in general or was not relevant to toxic or hazardous substances in particular. For example, the sections of the Federal Food, Drug and Cosmetics Act relevant to "devices" were omitted (because a device would rarely, if ever, be toxic in nature) as were the sections of the Clean Air Act dealing with automobile emission systems.* This compendium is not a general index to these acts, but is, rather, restricted specifically to record-keeping and reporting authorities. Other types of classes are included only where it is necessary to understand the means by which the agency informs itself on matters related to toxic substances. In all cases the standard by which a provision was included can be summarized as follows:

(A) (1) Will the agency possibly obtain significant information through the operation of the provision? and

* Most significantly, the compendium does not contain as a general class, regulatory authorities. Therefore, enforcement provisions, civil penalty provisions, court injunction provisions to restrain violations, and authorities to ban or regulate production or use are generally not included.

(2) Will the information be relevant to understanding the hazards, occurrence, or dispersal of a toxic substance in the environment? or

(B) Is the provision necessary or helpful to understanding other provisions which serve the purposes described in (A) above?

Immediately following this introduction we have included brief descriptions of each of the classes of authorities which should help to make the inclusions and omissions clear.

Whenever a substantial part of a section of an act was omitted, a single three point ellipsis was used to indicate the omission. When an entire section or more was omitted, an ellipsis of three asterisks centered on the page was used. However, these conventions do not apply to simple editing of the text which was usually done without the use of ellipses.

There are four aids to facilitate use of this compendium. The first, labeled Classes of Information-gathering Provisions, enumerates and then describes individually the seventeen classes of provisions (e.g., Subpoena authorities, Requirements to post warnings or affix labels, Requirements to conduct tests) that were culled from the acts. The second, labeled Authorities by Class, indicates, in chart form, the number of provisions in each act that are assigned to each class. This chart may be consulted to determine whether an act contains any provisions in a particular class. The next section, labeled Index to Statutes, lists and annotates by class, and within class by statute, the relevant statutory citations. Using this index, the user may easily scan all the acts for a particular class of provisions, or scan a particular act for all classes of provisions contained therein. Finally, in the texts of the acts, roman numerals appear in the left margin to indicate the precise location of each provision listed in the Index to Statutes. These roman numerals correspond to the seventeen classes listed in the section labeled Classes of Information-gathering Provisions.

When it was possible, an entire section or subsection was assigned to a class, and a roman numeral appears in the left margin next to the section number or subsection letter. That roman numeral does not occur again within that section unless used to highlight a particularly important passage. In these cases, the user will have to scan the entire section to find all the language relevant to the indicated class. This is particularly important in understanding the assignments made for the Federal Water Pollution Control Act (FWPCA). Section 104 of FWPCA, for example, assigns the Administrator seventeen major research projects and contains nine references to cooperation with other entities in carrying out the assigned research. Accordingly, the entire section is assigned to classes II and III. However, the research projects are not individually assigned to classes II and III, and, therefore, do not appear separately in the chart labeled Authorities by Class or the annotated index mentioned above.

Whenever necessary for clarity, a unit smaller than a subsection was assigned to a class. In these cases a roman numeral appears in the margin at the appropriate line in the text and the provision appears separately in the chart and the annotated index. The provisions are not assigned to sub-classes (e.g., VIII b or XII d) because annotation of the Index to Statutes better serves this purpose.

With the exception of the last two, all of the seventeen classes of information-gathering provisions are directly related to information development or dissemination. The exceptions are Category XVI, Relevant Definitions, and Category XVII, Other Relevant or Precedent Clauses, which includes other sections necessary for understanding the purposes or procedures of the respective acts.

It was necessary at several points, to include explanatory material not contained in an act. For example, other sections are often referred to in the text of an act, but usually only the section number is provided. Where it is helpful to the reader to know what the referenced section deals with we have included its title or a short descriptive phrase. Such editorial inclusions or other substantially editorial passages are enclosed in square brackets to identify them as such.

CLASSES OF INFORMATION-GATHERING AUTHORITIES

INFORMATION DEVELOPMENT

- I. Requirements to conduct tests
- II. Obligations and discretionary authorities of Federal agencies to develop information/guidelines/standards/criteria
- III. Obligations and discretionary authorities of Federal agencies to cooperate with other entities in developing information or for other purposes
- IV. Required or discretionary review by an advisory committee or public hearing
- V. Requirements to monitor:
 - a) compliance or quality
 - b) exposure levels
 - c) health effects

RECORD-KEEPING

- VI. Requirements established by rule to maintain records on:
 - a) operations and outputs
 - b) exposure levels
 - c) adverse health and environmental effects
 - d) administrative procedures
- VII. General and unspecified record-keeping or reporting authorities to be exercised "as necessary for the effective enforcement of the Act"

INFORMATION-GATHERING

- VIII. Authorities or requirements to inspect:
 - a) records
 - b) premises
- IX. Subpoena authorities
- X. Provisions to submit applications/petitions/certifications or to obtain permits/registrations/exemptions/waivers

XI. Requirements to give notice or certification

XII. Requirements established by rule to submit reports:

- a) on operations and outputs
- b) on exposure levels
- c) on adverse health and environmental effects
- d) on required studies
- e) as part of an application/petition/certification

XIII. Specific or general authorities to require submission of records and reports in response to directed inquiries (e.g., letters) without requiring either rules or subpoenas

Also see VII above

INFORMATION DISSEMINATION

XIV. Public availability of information and confidentiality provisions

XV. Requirements to post warnings or affix labels

Also see X above

OTHER

XVI. Relevant definitions

XVII. Other related or precedent clauses

DESCRIPTIONS OF THE CLASSES

I. Requirements to conduct tests

Most entries in this class are provisions authorizing requirements to conduct tests on chemical substances for safety, efficacy or environmental effects. Many such requirements occur in conjunction with other activities, as, for example, in FD&CA subsection 505(b) which requires the results of certain tests to be submitted with any new drug application. Authorities to require medical examination programs to detect adverse reactions are included under class V(c), Requirements to monitor: health effects. Requirements to test effluent discharges, ambient levels, and product or process compliance and/or quality are all collected under class V, Requirements to monitor.

II. Obligations and discretionary authorities of Federal agencies to develop information/guidelines/standards/criteria

Several of the acts, FWPCA being a prime example, require the agency to expend considerable resources developing certain information necessary to implementation of the act. Some of these requirements are straightforward research assignments for the agency, while others occur indirectly as an adjunct to another activity (e.g., the need to develop considerable new knowledge in establishing effluent guidelines under FWPCA.) These research assignments represent an extensive source of information on chemicals and their occurrence in the market or environment. Accordingly, these have been collected in class II.

III. Obligations and discretionary authorities of federal agencies to cooperate with other entities in developing information or for other purposes

With the exception of the Railroad Safety Act, each of the fifteen acts contains at least one requirement for the lead agency to cooperate with another specified agency or a general authority for discretionary cooperation with other agencies. The majority of such provisions (which do appear in the compendium) deal with interagency cooperation for the purpose of developing information, guidelines, standards or criteria. However, some provisions requiring or authorizing interagency cooperation are not relevant to information development, or are not relevant to toxic substances, and are therefore not included.

IV. Required or discretionary review by an advisory committee or public hearing

Several of the acts provide for review of technical problems by advisory committees, often at critical points in a decision

process. Because these committees frequently may represent significant avenues of input and analysis, the relevant statutory provisions are collected here. In addition, some of the acts provide for a similar use of public meetings and regional conferences. Such public input mechanisms which inform the agency or aid the agency in setting policy are also included. However, public hearings which occur as a matter of course in rule-making or in response to a public petition are often not included, as substantial technical input is less likely to come from such gatherings. In all cases where the agency may subpoena attendance, testimony, books or papers to the hearing, the provisions for the hearing are included.

V. Requirements to monitor:

- a) compliance or quality
- b) exposure levels
- c) health effects

The provisions in this class include monitoring by owners and operators as well as by states or federal agencies. These authorities can be differentiated into two classes: (1) authority to require specific types of monitoring or monitoring in connection with other specific requirements such as permits, and (2) general authority to require monitoring. There is also one act (CPSA) which contains an apparent prohibition on requiring quality control monitoring programs. Because this is directly relevant to monitoring authorities, it is also included here.

VI. Requirements established by rule to maintain records on:

- a) operations and outputs
- b) exposure levels
- c) health and environmental effects
- d) administrative procedures

All authorities to require specific types of information to be kept are collected into this class. "Administrative procedures" in (d), above, usually refers to requirements that a state or other entity maintain records on a process by which a decision or plan was reached or implemented. These include records of the administration of a state implementation plan (SDWA) and records of the development of a standard (CPSA). Also collected in this class are a few special provisions directly related to record-keeping authorities, such as the small business exemption contained in TSCA section 8.

VII. General and unspecified record-keeping or reporting authorities to be exercised "as necessary for the effective enforcement of the Act"

Any provisions of the acts which authorize general record-keeping or reporting requirements, without specifying what records are to be kept or reports submitted, are collected under this class of

authorities. General regulation writing authorities are also collected here because such authorities may include authority to require records or reports.

VIII. Authorities or requirements to inspect:

- a) records
- b) premises

With the exception of FFA, each act contains some authority to inspect premises or to obtain access to records for inspection and copying. These two types of inspection authority are collected together in this class, but differentiated by the annotations in the index so that either type may be searched separately from the other.

IX. Subpoena authorities

Most provisions for an agency to obtain testimony or records by subpoena or court order were extracted from the acts and appear in the text and index. However, in cases where the authority is not related to obtaining information on a toxic substance, it is not included. An example of such a case occurs in subsection 202(b)(4) of the Clean Air Act which authorizes the Administrator to subpoena records of automobile manufacturers in regard to pollution control equipment on new vehicles for the purpose of preparing an annual report to Congress. Since this is not relevant to chemical regulation, it is not included. We have also not included authorities for courts to subpoena information in a judicial review proceeding as such powers are meant to inform the court, and are not useful to an agency.

X. Provisions to submit applications/petitions/certifications or to obtain permits/registrations/exemptions/waivers

It is almost always the case that permit-type processes are an important means by which an agency gathers information. Several types of permit and registration processes are included in this class: some dealing with state implementation programs, while others apply to individual owners or operators. Permit programs which do not deal with toxic substances directly are not included. An example is section 404 of FWPCA which requires permits for discharge of dredged or fill material into the navigable waters of the United States. This process would almost certainly never develop information relevant to future regulation of a specific toxic substance.

XI. Requirements to give notice or certification

Reporting requirements that are automatically triggered by an event are collected into this class and termed generally as notices. Important examples are the section 5 premanufacture notice of TSCA and

the section 13 premarket notice of CPSA. However, this class also includes notices given to individuals as well as agencies. For example, section 8 of OSHA requires manufacturers to notify workers of excessive exposure, and section 14 of CPSA requires notification of conformance with a consumer product safety standard to appear on a product label to notify consumers of such conformance. Certain other certifications of conformance are closely related to the latter example and are also included. Some certification requirements, only tangentially related to the idea of notification, are also included here so that all certifications could be grouped together.

XII. Requirements established by rule to submit reports:

- a) on operations and outputs
- b) on exposure levels
- c) on adverse health and environmental effects
- d) on required studies
- e) as part of an application/petition/certification

Any provision in an act which requires that a report be submitted to an agency in response to a rule is included in this class if the report or information contained in the report is related to chemical regulation. Reports required of state agencies on their activities in implementing an act are also included in this class. Non-specific authorities to require reports are included in class VII because such authorities usually occur as a combined general authority to require records and/or reports. Authorities to require reports from individuals by letter are collected in class XIII.

XIII. Specific or general authorities to require submission of records and reports in response to directed inquiries (e. ., letters) without requiring either rules or subpoenas

Letter-writing authority is a complex issue and a determination that such authority has been granted by Congress often requires consideration of the legislative history as well as the act. No such detailed efforts are implied by inclusion of a provision in this class. Rather, clauses which seem to indicate such authority are collected here along with authorities to require information by special order, which is a closely related mechanism. The General Counsel of the lead agency should be consulted to determine if letter-writing authority actually exists under a specific act.

XIV. Public availability of information and confidentiality provisions

Provisions in the acts which affect the public availability of information that is collected under any of the provisions appearing in the compendium are collected in this class. Such provisions may, for

example, specify that certain information shall be public or that it shall be subject to the confidentiality protections of another law such as the Administrative Procedures Act. Provisions that require an agency to develop or prepare information for public dissemination are also included.

XV. Requirements to post warnings or affix labels

Any labeling requirement, or other provision relevant to a labeling requirement, is included in this class. Requirements to post signs at a workplace are also included because the intent is so closely related. (Some of the provisions collected into class X deal with labels certifying conformance with a standard. That class should be consulted in regard to such labeling requirements.)

XVI. Relevant definitions

This section includes any definitions necessary to understand the sections of the acts that are included in the compendium. Some of the terms contained in this class may not be used in the compendium but the definitions are helpful to understanding the scope and intent of the act. This is particularly true of SDWA and FHSA.

XVII. Other related or precedent clauses

Any provision which could not reasonably be placed in one of the other classes, but is necessary to understand the scope or application of an act, is included here. These provisions are not referenced at the related point in the text because it would not often be possible. This class must be scanned for relevance to any sections of interest in an act. As a matter of course, provisions dealing with imports and exports are included here because such sections usually deal with application of several parts of the act to imports and exports, and are therefore not uniquely assignable to a single class of authorities. General regulation-writing authorities may reasonably have been gathered into this class. However, because the central theme of this compendium is record-keeping and reporting authorities, such regulation-writing provisions have been separately included in class VII, General and unspecified record-keeping or reporting authorities to be exercised "as necessary for the effective enforcement of the Act."

AUTHORITIES BY CLASS

	I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII	XIV	XV	XVI	XVII
<u>TSCA</u>	4	10	10	1	3	5	2	2	1	2	6	5	1	7	1	4	7
<u>RCRA</u>	-	8	7	1	1	6	1	1	1	3	2	3	1	2	2	7	3
<u>FIFRA</u>	2	3	4	2	1	-	2	2	1	4	2	5	1	4	6	9	3
<u>CAA</u>	2	13	3	6	5	1	2	1	1	10	1	8	1	4	-	2	2
<u>FWPCA</u>	-	13	5	6	3	1	3	2	2	5	4	2	1	3	-	10	5
<u>SDWA</u>	-	2	2	-	3	2	3	3	-	3	-	-	-	1	-	5	-
<u>FD&CA</u>	6	12	3	8	3	7	3	10	-	9	2	13	4	6	11	22	4
<u>OSHA</u>	2	7	4	4	3	3	3	7	1	1	1	4	-	4	2	7	5
<u>FMSHA</u>	1	5	-	4	3	4	1	6	2	2	1	2	-	5	3	5	2
<u>CPSA</u>	3	6	1	5	1	1	1	3	1	1	6	1	1	4	2	7	3
<u>FHSA</u>	-	1	1	-	-	1	1	3	-	1	-	-	-	2	3	9	5
<u>FFA</u>	1	-	1	1	-	-	2	-	1	-	-	-	-	1	-	-	1
<u>PPPA</u>	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-	-	-
<u>HMTA</u>	-	5	1	-	1	-	1	2	2	3	-	1	2	4	1	2	5
<u>RSA</u>	-	2	-	-	2	1	2	3	1	1	-	1	-	-	-	-	-

INDEX TO STATUTES

I Requirements to Conduct Tests

TSCA

- 4 testing requirements
- 5(a) submission of test data
- 6(a)(4) authority to require tests to assure compliance
- 30 annual report to Congress on testing requirements

RCRA

FIFRA

- 3(c)(1)(D) pesticide registration - submission of test results
- 5(d) experimental use permits - required studies

CAA

- 111(j)(1)(A) waivers - general authority of Administrator to require tests
- 211(b)(2)(A) registered fuels - tests of health effects - manufacturer

FWPCA

SDWA

FD&CA

- 408(d)(1)(C) investigations of pesticide safety - petition for a tolerance
- 408(d)(1)(D) studies of pesticide residue - petition for a tolerance
- 409(b)(2)(E) studies of additive safety - petition to establish safety
- 505(b) new drug applications - tests for safety and efficacy
- 505(i)(1) preclinical investigations of new drugs required
- 512(b) new animal drug application - tests

OSHA

- 6(b)(7) safety and health standards - medical exams and other test requirements
- 20(a)(5) Secretary's research projects - authority to establish medical exam programs and other tests

FMS&HA

101(a)(7) health and safety standards may require medical exams and other tests

CPSA

7(d)(3)(A) developing a consumer product safety standard - required tests
14(a) certificate based on tests
14(b) authority to require tests

FHSA

FFA

5(d) general authority to require tests of fabrics

PPPA

HMTA

RSA

II Obligations and Discretionary Authorities of Federal Agencies to Develop Information/Guidelines/Standards/Criteria

TSCA

- 4(b)(2)(A) prescribing test methodologies
- 4(b)(5) findings with respect to testing rules
- 4(g) developing testing standards - petition
- 5(a)(2) prescribing significant new use criteria
- 5(b)(4) list of chemicals - possible unreasonable risks
- 6(c) regulating chemicals - required statement
- 8(b) developing the Inventory
- 9(a) other agency regulation - developing information
- 10 research, development, collection, dissemination
- and utilization of data
- 25 classification, storage and retrieval study

RCRA

- 1008(a) information and guidelines
- 3001(a) & (b) designating hazardous wastes and criteria
- 3002 standards applicable to generators
- 3003 standards applicable to transporters
- 3004 standards applicable to handlers
- 8001 research, demonstration, training and other activities
- 8002 special studies
- 8003 coordination, collection and dissemination of information

FIFRA

- 6(b) registration suspension - required considerations
- 20 research and monitoring - Administrator's duties
- 25(c)(6) authority to establish official names for pesticides

CAA

- 103 several research projects for the Administrator
- 108 air quality criteria and control technology - information development
- 111 standards of performance for new stationary sources
- 112 national emission standards for hazardous air pollutants
- 153 ozone protection - studies by EPA
- 154 ozone protection - research and monitoring by other agencies
- 211(b) registered fuels - development of test protocols

211(c)(2)	regulation of fuels and additives - required considerations
307(d)(3)	factual background of any rule promulgated
309	Administrator's comments on other agency actions
319	establishment of national air quality monitoring guidelines
120 of P.L. 95-95	Administrator's studies of several pollutants
403 of P.L. 95-95	several studies required of Administrator

FWPCA

104	research, investigations, training and information
105	research and development of pollution control techniques
115	identifying in-place pollutants
301	developing effluent limitations
303(d)(1)(A)	required effluent limitation survey by States
304	several requirements to develop criteria and information
305	required water quality inventory by States
306	national standards of performance
307	toxic and pre-treatment effluent standards
311(b)(2)(A)	designation of hazardous substances
401(b)	supplying information and advice to other entities
403	developing ocean discharge criteria
516	required biennial report

SDWA

1412	large study of drinking water safety required
1442	general authority to conduct studies and research

FD&CA

401	development of definition and standard for a food
406	tolerances for poisonous ingredients in food
408	tolerances for pesticides on raw agricultural commodities
408(j)	temporary tolerance for experimental permits
409(c)	petition to establish additive safety - development of conditions (standard of use)
409(d)	Secretary may establish additive safety on his own initiative
505(d)	new drug application - required findings
508	designating official names for drugs
702	general authorities necessary to conduct investigations
702(d)	developing information for the Commissioner of Patents

706(b)(5) color additive safety - required considerations
706(b)(7) color additives - tolerance

OSHA

4(b)(3) unnecessary duplication - interagency co-
operation
6 developing occupational safety and health
standards
6(b)(7) worker medical exams - reimbursement by HEW
20 research and related activities
20(a)(6) Toxic Substances List required
22 NIOSH - information development responsibilities
24 statistics - development

FMS&HA

101(a) Secretary required to develop improved health
or safety standards
101(a)(6)(A) factual basis required for standards
101(a)(6)(B) determination of toxicity
101(a)(7) research - medical examinations
501 several research projects for the Secretary

CPSA

5 product safety information and research
7 consumer product safety standards
9(b) establishing standards - factual basis
9(c) establishing standards - required findings
27(h) consumer product testing and research facilities
27(j) biennial report to Congress

FHSA

13(b) preparing results of investigations for public
availability

FFA

PPPA

HMTA

109(a) general information development authority -
Secretary
109(d) research facilities and data centers
109(e) annual report by Secretary
304(a)(4) special studies by Board
304(a)(8) evaluation of safeguards

RSA

- 202(a) developing standards and regulations for railroad
 safety
208(a) general authority to develop information, etc.

III Obligations and Discretionary Authorities of Federal Agencies to Cooperate with Other Entities in Developing Information or for Other Purposes

TSCA

4(b)(2)(A) prescribing epidemiological studies
6(c) cooperative administration
8(a)(3)(B) small manufacturer definition
9 relationship to other Federal laws
9(d) cooperative enforcement
10 research
10(b)(1) interagency information-coordination and
exchange committee
10(g) exchange of data
26 cooperative administration
27 development and evaluation of test data

RCRA

1006 integration with other acts
3003 transportation of hazardous waste
6003 cooperation with EPA
8001(a) studies - cooperation with FEA, ERDA, and FPC
8001(b) management program - coordination with other
acts
8002(f) mining waste study - cooperation with Interior
Department
8003(f) information collection and dissemination -
cooperation with States and local authorities

FIFRA

6(b) suspension actions - cooperation with USDA
17(d) international research and regulation -
Administrator's involvement
21(a) promulgating regulations - Secretary of
Agriculture's comments
25(a)(2) general regulation-writing authority -
cooperation with USDA

CAA

103 the Administrator's research projects - co-
operation with other agencies
323(e) interagency cooperation with the National
Commission on Air Quality
402 of P.L.
95-95 establishment of Task Force on Environmental
Cancer and Heart and Lung Disease

FWPCA

- 102(a) comprehensive program development - joint investigations of pollution
- 104 several cooperative research projects
- 105 R&D - control techniques - grants
- 115 cooperation with Secretary of the Army to remove in-place pollutants
- 501(b) use of other agency personnel

SDWA

- 1412 Administrator - cooperation with National Academy of Sciences - maximum contaminant level study
- 1442 Administrator must provide technical assistance to States

FD&CA

- 702(c) records of other agencies available to Secretary
- 702(d) supplying information to the Commissioner of Patents
- 707 developing tests and methods

OSHA

- 7(c)(1) general authority to use other agencies' resources
- 8(c)(3) requiring records of exposures - cooperation with EEW
- 20 several cooperative research or development projects
- 24 statistics development - EEW and Department of Labor

FMS&HA

CPSA

- 29 cooperation with States and with other Federal agencies

FHSA

- 10(b) development of import regulations (section 14) - cooperation with Secretary of the Treasury

FFA

5(d)(2)

general authority to cooperate with any unit
of local, State or Federal government, or any
individual

PPPA

HMTA

105(b)

cooperation between Secretary and ICC

RSA

IV Required or Discretionary Review by an Advisory Committee or Public Hearing

TSCA

4(e) Interagency Testing Committee established

RCRA

3008(b) public hearing - enforcement actions

FIFRA

6(c) & (d) registraton suspension - public hearing and scientific review

CAA

103(e) significant air pollution problem - regional conference

109 air quality standards - scientific review committee

112(b)(1)(B) hazardous air pollutant emission standards - required public hearing

117 advisory committees

165 significant deterioration - permit hearing

323 National Commission on Air Quality

FWPCA

104(a)(3) public investigations of pollution

104(a)(4) research programs and proposals - advisory committee review

303(c)(1) water quality standards - public hearing

401(a)(1) permit application - certification - public hearing

401(a)(2) certification - public hearing requested by other States

515 Effluent Standards and Water Quality Information Advisory Committee

SDWA

FD&CA

408(d)(3) & (e) petition for a pesticide tolerance - advisory committee

409(f)(1) additive safety - hearing

512(c) & (e) new animal drug - hearings and advisory committees

512(m)(2), animal feeds - hearings and advisory
(m)(4)(B) committees
706(b)(5)(C) color additive safety - advisory committee

OSHA

6(b)(1) rule development - advisory committee
6(d) variance from a safety and health standard -
public hearing
7 National Advisory Committee on Occupational
Safety and Health and other advisory committees
22 establishment of NIOSH

FMS&HA

101(a)(1) standard development - advisory committee
101(a)(3) standard development - public hearing
102(c) general authority to appoint advisory committees
103(b) accident investigation may include public hearing

CPSA

10(c) petition for consumer product safety rule -
hearing
12(d)(1) Product Safety Advisory Council
12(d)(3) Product Safety Advisory Council may conduct
hearings
27(a) discretionary authority to conduct inquiries
and hearings
28 establishment of the Product Safety Advisory
Council

FHSA

FFA

17 National Advisory Committee for the Flammable
Fabrics Act

PPPA

6 technical advisory committee for general
purposes

HMTA

RSA

V Requirements to Monitor:

- a) compliance or quality
- b) exposure levels
- c) health effects

TSCA

- 6(a)(4) general authority to require monitoring
- 6(b) quality control
- 10(a) monitoring by Administrator

RCRA

- 3004(2) handlers - non-specific monitoring authority

FIFRA

- 20(b)&(c) National Monitoring Plan

CAA

- 110(a)(2)(C) implementation plans - monitoring by States
- 110(a)(2)(F)
 - (ii) implementation plans - monitoring by owners and operators
- 114(a)(1) general authority to require monitoring by owners and operators
- 165(a)(7) significant deterioration - monitoring requirements
- 319 establishment of national air quality monitoring program

FWPCA

- 104(a)(5) monitoring water quality
- 308(a)(A) monitoring by owners and operators of point sources
- 401(d) permit - required certification - monitoring requirements

SDWA

- 1413(a)(2) monitoring by States required under public water supply programs
- 1421(b)(1)(C) monitoring provisions required as part of State underground injection program
- 1445(a) general authority to require monitoring

FD&CA

409(b)(3) petition to establish additive safety -
description of manufacturing controls
512(e)(2)(B) new animal drugs - quality control
512(m) animal feeds - quality control

OSHA

6(b)(7) safety and health standards - medical
examination program and monitoring requirements
8(c)(3) records of required (6(b)(7)) monitoring
20(a)(5) Secretary's research projects - authority
to require employers to monitor exposures and
conduct medical examination programs

FMS&HA

101(a)(7) health and safety standards may contain
monitoring requirements and medical examination
requirements
202(a) monitoring respirable dust required
203 x-ray monitoring of pneumoconiosis development

CPSA

7(a)(2) monitoring product quality prohibited

FHSA

FFA

PPPA

HMTA

106(a) monitoring safety procedures

RSA

206(a)(3) State monitoring of compliance with regulations
206(e) Secretary monitoring State efforts

VI Requirements Established by Rule to Maintain Records on:

- a) operations and outputs
- b) exposure levels
- c) adverse health and environmental effects
- d) administrative procedures

TSCA

- 6(a)(4) records of processes
- 8 authority to require several types of records
- 8(a)(2) several types of records
- 8(a)(3) small manufacturer provisions
- 8(c) records of allegations of adverse reactions

RCRA

- 3002(1) generators - records of outputs
- 3002(5) generators - manifest system
- 3003(1) transporters - records of operations
- 3003(3) transporters - manifest system
- 3004(1) handlers - records of operations
- 3004(2) handlers - manifest system

FIFRA

CAA

- 110(a)(2)(F)
 - (11) authority to require reports of effluents (records implied)

FWPCA

- 308(a)(A)(1) general authority to require owners and operators of point sources to keep records

SDWA

- 1413(a)(3) records of activities required of States
- 1422(b)(1)(A)
 - (11) records of activities required of States

FD&CA

- 505(e) failure to maintain required records - withdrawal of approval (new drug)
- 505(i)(3) records required to establish efficacy of a new drug
- 505(j)(1) records of clinical experience - approved new drugs

- 512(e)(1) &
(e)(2)(A) new animal drugs - general authority to
require records
- 512(j) new animal drug research - general authority
to require records
- 512(m)(4)
(B)(1) animal feeds - records

OSHA

- 8(c)(2) general authority to require records of worker
deaths, injuries and illnesses
- 8(c)(3) records of employee exposure required
- 20(a)(5) Secretary's research projects - authority to require
employers to record exposures

FMS&HA

- 103(c) records of exposure required
- 103(d) records of accidents and investigations
- 303(a) inspection of ventilation equipment - records
- 312(a) required map of mine

CPSA

- 7(d)(3)(C) records of standards development process

FHSA

- 5(b) guarantees (manifest system)

FFA

PPPA

HMTA

RSA

- 206(b)(3) records kept by States

VII General and Unspecified Record-keeping or Reporting Authorities to be Exercised "As Necessary for the Effective Enforcement of the Act"

TSCA

8(a)(1) general record-keeping and reporting authority
8(a)(3) small manufacturer record-keeping and reporting authorities

RCRA

2002(a)(1) general regulation-writing authority

FIFRA

8(a) general authority to require manufacturers to keep records
25(a)(1) general regulation-writing authority

CAA

114(a)(1) general authority to require records and reports of owners and operators
301 general regulation-writing authority

FWPCA

308(a)(A) general authority to require records and reports from point source operators
402(a)(2) NPDES permits - record-keeping and reporting requirements
501 general regulation-writing authority

SDWA

1421(b)(1)(C) general record-keeping and reporting authority required as part of State program
1445(a) general authority to require records and reports
1450 general regulation-writing authority

FD&CA

505(i)(3) clinical drug studies - general authority to require records and reporting
505(j)(1) general authority to require record-keeping and reporting - approved new drug
701(a) general regulation-writing authority

OSHA

8(c)(1) general authority to require records
8(g)(2) general regulation-writing authority
24(e) general authority to require reports from employers

FMS&HA

103(h) general authority to require record-keeping and reporting

CPSA

16(b) general authority to require record-keeping and reporting

FHSA

10(a) general regulation writing authority

FFA

4(c) general authority to obtain reports and records by regulation or subpoena
5(c) general authority to require record-keeping by regulation

PPPA

HMTA

109(b) general record-keeping and reporting authority of Secretary

RSA

206(b)(4) annual report by States - "such other information as the Secretary may require..."
208(a) general authority to require record-keeping and reporting

VIII Authorities or Requirements to Inspect:

- a) records
- b) premises

TSCA

- 8(c) inspection and copying of records
- 11(a)&(b) general authority to inspect premises and records

RCRA

- 3007 general authority to inspect premises and records

FIFRA

- 8(b) authority to inspect records of certain types
- 9 authority to inspect establishments

CAA

- 114(a) (2) authority to inspect records and monitoring equipment and to sample emissions

FWPCA

- 308(a) (B) authority to inspect premises and required records of point sources
- 311(m) authority to inspect vessels

SDWA

- 1413(a) (2) inspection authority required as part of public water systems program
- 1421(b) (1) (C) inspection provisions required as part of State underground injection program
- 1445(b) (1) general authority to inspect records and premises

FD&CA

- 505(e) refusal to permit inspection of required records - new drugs
- 505(j) (2) inspection of records required on new drugs
- 510(h) inspection of drug producer's premises and records
- 512(e) (2) (A) & (1) (2) new animal drugs - inspection of records
- 512(m) (4) (B) (1) & (m) (5) (B) animal feeds - inspection of records

702(e) general authority to execute and serve search warrants
 703 general authority to inspect records relevant to interstate shipments
 704 general authority to inspect premises

OSHA

2(b) Secretary's research projects - general authority to inspect
 8(a) general authority to inspect premises
 8(c)(1) general authority to inspect required records
 8(c)(1) authority to require periodic inspections
 8(f) employee right to request an inspection
 8(g)(2) general regulation-writing authority - inspections
 18(c)(3) state plans must include inspection authority

FMS&HA

103(a) broad authority to inspect mines
 103(g)(1) miner's right to an immediate inspection
 103(i) especially hazardous conditions - weekly inspection required
 202(g) interim dust standard - authority to make spot inspections
 303(d)(1) inspection before each shift
 303(e) inspection of each working section during each shift

CPSA

7(d)(3)(C) authority to inspect records of standards development process
 16(a) general authority to inspect premises
 16(b) general authority to inspect records to determine compliance

FHSA

11 general authority to inspect premises
 12 general authority to inspect records of interstate shipments
 14 obtaining samples of imports

FFA

PPPA

HMTA

109(c) inspections by Secretary
 304(b)(2) inspections by National Transportation Safety Board

RSA

206(e) general inspection authority
208(a) general inspection authority
208(c) general authority to inspect equipment and records

IX Subpoena Authorities

TSCA

11(c) general subpoena authority

RCRA

3008(b) subpoenas - enforcement actions and public hearings

FIFRA

6(d) registration suspension hearing - subpoena authority

CAA

307(a)(1) subpoena authority for several specific purposes

FWPCA

509(a)(1) water quality inventory - subpoena power
509(a)(2) effluent limitations and process information - subpoena power

SDWA

FD&CA

OSHA

8(b) requiring testimony and production of evidence by court order

FMS&HA

101(a)(3) standard development - public hearing
103(b) accident investigation - public hearing

CPSA

27(b)(3)&(4) general subpoena authority

FHSA

FFA

4(c) general authority to subpoena testimony,
 books, records and other writings

PPPA

HMTA

109(a) subpoenas by Secretary
304(b)(1) subpoenas by National Transportation Safety
 Board

RSA

208(a) general authority to issue subpoenas

X Provisions to Submit Applications/Petitions/Certifications or to
Obtain Permits/Registrations/Exemptions/Waivers

TSCA

- 4(g) petition for test standards
- 5(h) exemptions from notice and data requirements

RCRA

- 3004(7) standards applicable to handlers - permits
- 3005 permits for treatment, storage or disposal of hazardous wastes (handlers)
- 3010(a) registration of generators, transporters and handlers ("preliminary notification")

FIFRA

- 3 registration of pesticides
- 4 restricted uses - certification of applicators
- 5 experimental use permits
- 7 registration of manufacturing establishments

CAA

- 110(a)(2)(D) implementation plans - permit program
- 110(a)(4) implementation plans - permit requirement
- 110(j) implementation plans - permit requirement
- 111(j)(1)(A) waivers from the requirements of section 111 - encouraging innovation
- 112(c)(1)(B) waivers from hazardous air pollutant emission standard
- 165 significant deterioration - pre-construction requirements
- 165(a)(8) permit - best available technology certification by Administrator
- 172(b)(6) non-attainment areas - permits required
- 173 non-attainment areas - permit requirements
- 211 registration of fuels and additives

FWPCA

- 301(c) & (g)-(1) applications for modifications of effluent limitations
- 401(a) application/permit - required certification
- 402 NPDES - permits for discharges
- 403(a) NPDES - ocean discharge permits

SDWA

1421(b)(1)(A) underground injection permits
1422(b)(1)(A) application for approval of State underground
injection program

FD&CA

408(d) petition to establish a pesticide tolerance
408(d)(2) petition for a tolerance - required certification
from USDA
409(b) petition to establish safety of a food additive
409(i) additives - exemptions for investigational use
505 new drug applications
505(i) new drugs - exemptions for investigational use
510 registration of drug manufacturers
512 new animal drug and animal feed applications
706 listing food color additives

OSHA

6(d) application for a variance from a standard

FMS&HA

109(d) registration of mines and operators
202(b)(3) permit for noncompliance with interim dust
standard for permit

CPSA

10 petition for consumer product safety rule

FHSA

3(d) general authority to exempt substances from require-
ments of FHSA or its regulations

FFA

PPPA

HMTA

106(b)&(c) registration of transporters and container
manufacturers
107 application for exemption from the Act

RSA

206(a) State participation - required annual certification

XI Requirements to Give Notice or Certification

TSCA

5	premanufacture notices - contents
6(a)(7)	notice of unreasonable risk
6(b)(2)	public notice of hazard
7(b)(2)	public notice of imminent hazard
8(e)	notice of substantial risk
12(b)	notice of intent to export

RCRA

3002(4)	notifying handlers and transporters of waste composition
3010	hazardous waste handlers - notification (registration with EPA)

FIFRA

12(a)(1)(P)	human studies - notifying subjects of nature of study
17(b)	exports - notice to foreign governments

CAA

111(j)(1)(A)	waivers - notice of unusual emissions
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FWPCA

311(b)(5) & (c)(2)(D)	oil and hazardous substances - notice of spill
402(b)(8)	treatment works - changes in amounts or types of introductions - notice
402(d)	notice of each permit application received by a State

SDWA

FD&CA

408(1)	USDA certification of pesticide usefulness
505(i)(2)&(3)	clinical tests of drugs - required certifications

OSHA

8(c)(3)	notice to employees of excessive exposures to toxic materials
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FMS&HA

103(c)	notifying miners of excessive exposure
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CPSA

- 13(a) premarket notice required
- 14(a)(1) certification of conformance with a standard
- 15(b) notice of substantial product hazard
- 15(c) public notice of substantial product hazard
- 27(e) providing consumers with technical and performance data by notice
- 14(c)(3) requiring certification of conformance on a label

FHSA

FFA

PTPA

HMTA

RSA

XII Requirements Established by Rule to Submit Reports:

- a) on operations and outputs
- b) on exposure levels
- c) on adverse health and environmental effects
- d) on required studies
- e) as part of an application/petition/certification

TSCA

- 4(b)(1) reports of preliminary test data
- 5(b)(2)(A) testing data submission
- 5(d)(1)(A) contents of premanufacture notice
- 8(a)(2) illustrative list of information that may be required
- 8(d) health and safety studies

RCRA

- 3002(6) generators - reports of outputs
- 3004(2) handlers - unspecified reporting (probably regarding manifest system)
- 3005(b) reports of operations - permit application

FIFRA

- 3(c)(2) data in support of pesticide registration
- 5(d) experimental use permits - reports on required studies
- 6(a)(2) submission of adverse effects information
- 7(c) establishment registration - information required
- 11(a) prohibition against requiring records or reports of private applicators

CAA

- 110(a)(2)(C) air quality monitoring - reports by States
- 110(a)(2)(F) reports of emissions
- (11)
- 110(a)(4) permit application - general authority of State to require information
- 111(j)(1)(A) waivers - required information and reports of tests
- 165(a)(6) permit process - required analysis of secondary impacts
- 165(e)(1) permit process - required analysis of primary impacts
- 172 implementation plan - required inventory of emissions
- 211(b)(2)(B) registration of fuels - required information

FWPCA

- 305 required water quality study - biennial report to Administrator
308(a)(A)(ii) general authority to require owners and operators of point sources to make reports

SDWA

FD&CA

- 408(d)(1) reports of investigations made on pesticides - petition for tolerance
409(b)(2)(E) reports of investigations made on additives - petition to establish safety
505(b) reports of investigations made on new drugs to establish safety and efficacy
505(e) failure to make required reports - withdrawal of approval (new drug)
505(i)(1) reports of preclinical studies of new drugs required
505(j) drug producers - semiannual list of products
510(j)(3) special list of products
512(b) new animal drug applications - contacts
512(d)(1)(E) new animal drug applications - efficacy
512(e)(2)(A) &(j)&(1) new animal drug applications - general authority to require reports
512(m) animal feeds - general authority to require reports

OSHA

- 8(c)(2) authority to require reports on work-related deaths, injuries and illnesses
18(c)(7) State plans must include reporting requirements
18(c)(8) State plans - general authority to require States to submit reports
20(a)(5) Secretary's research projects - authority to require employers to report exposures

FMS&HA

- 103(d) records of accidents and accident investigations - required annual report
202(a) submitting dust samples and reporting working conditions

CPSA

- 27(e) requiring submission of technical and performance data by rule

FHSA

FFA

HMTA

106(b) annual report of hazardous materials handled

RSA

206(b) annual certification by State - required report

XIII Specific or General Authorities to Require Submission of Records and Reports in Response to Directed Inquiries (e.g., Letters) Without Requiring Either Rules or Subpoenas

TSCA

8(c) records of allegations of adverse reactions

RCRA

3007(a) furnishing records

FIFRA

7(c)(2) requesting shipping data from individual manufacturers

CAA

114(a)(1) authority to require any information from an owner or operator

FWPCA

308(a)(A) authority to require reports, records and other information

SDWA

FD&CA

510(j)(1)(B)
(1) obtaining copies of advertisements for a particular drug
510(j)(1)(C) obtaining a quantitative ingredient list for a particular drug
512(d)(2) new animal drug - obtaining records and reports by special order
512(m)(5)(A) animal feeds - obtaining records and reports by special order

OSHA

FMS&HA

CPSA

27(b)(1) requiring reports and answers by special order

FHSA

FFA

PPPA

HMTA

109(b) general letter-writing authority for the
Secretary
304(b) (9) general letter-writing authority for Board

RSA

XIV Public Availability of Information and Confidentiality Provisions

TSCA

4(d)	public notice of receipt of testing data
5(b)(3)	public availability of test data
5(d)(1)	public availability of premanufacture notices
5(d)(2)	publication of notice
5(d)(3)	publication of list of premanufacture notices received
5(g)	statement of reasons for not taking action
14	disclosure of data

RCRA

3007(b)	public availability of inspection data
8003(e)	required program for rapid dissemination of information

FIFRA

6(d)	scientific review of registration suspension - report public
7(d)	production data confidential
10	trade secrets and other protected information
12(a)(1)(D)	prohibited acts - unauthorized use of information

CAA

110(a)(2)(F)	reports of emissions available to public
(11)	information from inspections - public availability
114(c)	availability
211(b)	fuels and additives - health effects studies not confidential
307(a)(1)	public availability of subpoenaed information

FWPCA

308(b)	confidentiality of information gathered during an inspection
402(j)	permit applications - available to public
509	confidentiality of subpoena information

SDWA

1445(d)(1) confidentiality of trade secret information
acquired under the Act

FD&CA

301(j) confidentiality of most information collected
under the Act

408(f) pesticide tolerance petition - confidentiality
of data

510(f) drug producer - registration data

705(b) dissemination of information

708 general confidentiality provisions

OSHA

6(b)(7) confidentiality of worker medical exams

8(c)(3) employee access to records of required
monitoring

8(g)(1) authorization to publish any information
obtained under the Act

15 confidentiality of trade secrets

FMS&HA

101(a)(7) confidentiality of medical examinations

103(c) miner access to records of exposure

103(d) public availability of records of accidents
and investigations

103(h) Secretary may compile and publish majority
of data collected under the Act

312(b) confidentiality of mine map

CPSA

6 public disclosure of information

7(d)(3)(C) records of standards development

25(c) public availability of information

28(c) proceedings of Product Safety Advisory Council
- public

FHSA

4(h) unauthorized use of trade secret information
prohibited

13 imminent danger situations and general public
availability of data

FFA

4(c) confidentiality of trade secret information

HMTA

106(b)	transporters and container manufacturers -
	registration information
107(a)	safety analyses - data
304(b)(9)	public availability of information submitted
	to Board
306	public availability of information submitted
	to Board

RSA

XV Requirements to Post Warnings or Affix Labels

TSCA

- 6(a)(3) general authority to require labeling

RCRA

- 3002(2) generators - labeling hazardous waste containers
3003(a)(2) transporters - labeling requirements

FIFRA

- 3(c)(1)(C) pesticide registration - submitting labeling
3(c)(5)(B) pesticide registration - approval of labeling
3(d)(1)(A) general uses and restricted uses - different labeling
12(a)(1)(G) pesticide use inconsistent with labeling prohibited
25(c)(3) packaging and labeling standards
25(c)(5) requiring a pesticide to be colored or discolored

CAA

FWPCA

SDWA

FD&CA

- 301(o) sending copies of all labeling to a practitioner
403 definition of misbranded food - labeling requirements
502 definition of misbranded drug or device - labeling requirements
512(d)(1)(G)&(e)(2)(C)&(i) new animal drugs - labeling
512(m)(1)&(m)(3)(D)&(m)(4)(B) animal feeds - labeling
601(a) cosmetics - labeling coal tar hair dyes
601(b) cosmetics - "misbranded" definition

OSHA

- 6(b)(7) safety and health standards - labeling requirements
8(c)(1) posting notice of employee protections and obligations under the Act

FMS&HA

- 101(a)(7) health and safety standards must include workplace warnings
- 109(a) required posting of orders and decisions
- 303(d)(1) posting danger signs as a result of inspections

CPSA

- 7(a)(1)(B) general authority to require labels
- 14(c) general authority to prescribe use and form of labels

FHSA

- 2(p) general labeling requirements
- 3(b) special labeling requirements
- 3(c) exemptions from unnecessary labeling

FFA

PPPA

HMTA

- 105(a) general authority to require labeling

RSA

XVI Relevant Definitions

TSCA

3(1)	"Administrator"
3(6)	"health and safety study"
3(12)	"standards for the development of test data"
26(c)	"category of chemical substances"

RCRA

1004(1)	"Administrator"
1004(3)	"disposal"
1004(5)	"hazardous waste"
1004(12)	"manifest"
1004(27)	"solid waste"
1004(33)	"storage"
1004(34)	"treatment"

FIFRA

2(e)(1)	"certified applicator"
2(e)(2)	"private applicator"
2(e)(3)	"commercial applicator"
2(n)	"ingredient statement"
2(p)(1)	"label"
2(p)(2)	"labeling"
2(q)	"misbranded"
2(x)	"protect health and the environment"
2(bb)	"unreasonable adverse effects on the environment"

CAA

112(a)(1)	"hazardous air pollutant"
171(1)	"reasonable further progress"

FWPCA

306(a)(1)	"standard of performance"
306(a)(2)	"new source"
306(a)(3)	"source"
311(a)(1)	"oil"
311(a)(14)	"hazardous substance"
502(11)	"effluent limitations"
502(13)	"toxic pollutant"
502(15)	"biological monitoring"
502(18)	"industrial user"
502(19)	"pollution"

SDWA

1401(1)	"primary drinking water regulation"
1401(2)	"secondary drinking water regulation"
1401(3)	"maximum contaminant level"
1421(d)(1)	"underground injection"
1421(d)(2)	"underground injection which endangers a drinking water source"

FD&CA

201(c)	"Department"
201(f)	"food"
201(g)	"drug"
201(i)	"cosmetic"
201(j)	"official compendium"
201(k)	"label"
201(m)	"labeling"
201(n)	"misbranded"
201(p)	"new drug"
201(q)	"pesticide chemical"
201(r)	"raw agricultural commodity"
201(s)	"food additive"
201(t)	"color additive"
201(u)	"safe"
402	"adulterated food"
403	"misbranded food"
409	"unsafe food additive"
501	"adulterated drug or device"
502	"misbranded drug or device"
510(a)(1)	"manufacture, preparation, propagation, compounding or processing"
512(d)(3)	"substantial evidence"
601	"adulterated cosmetics"

OSHA

3(1)	"Secretary"
3(8)	"occupational safety and health standard"
3(9)	"national consensus standard"
3(10)	"established Federal Standard"
3(11)	"Committee"
3(12)	"Director"
3(13)	"Institute"

FMS&HA

3(a)	"Secretary"
3(j)	"imminent danger"

3(k) "accident"
3(l) "mandatory health or safety standard"
3(n) "Administration"

CPSA

3(a)(1) "consumer product"
3(a)(2) "consumer product safety rule"
3(a)(3) "risk of injury"
3(a)(7) "private labeler"
12(a) "imminently hazardous consumer product"
13(b) "new consumer product"
15(a) "substantial product hazard"

FHSA

2(d) "Commission"
2(f) "hazardous"
2(g) "toxic"
2(h) "highly toxic"
2(i) "corrosive"
2(j) "irritant"
2(k) "strong sensitizer"
2(p) "misbranded hazardous substance"
2(q) "banned hazardous substance"

FFA

PPPA

HMTA

103(2) "hazardous material"
103(3) "Secretary"

RSA

XVII Other Related or Precedent Clauses

TSCA

2(b)	policy - development of data
4(f)	receipt of test data - required actions
5(e)(1)(A)	insufficiency of information
6	regulation of hazardous substances and mixtures
8(a)(2)	small manufacturer exemption
12	exports
13	imports

RCRA

3003(4)	prohibited acts
3008	enforcement provisions
8002(1)	studies - completion dates

FIFRA

6	administrative review and suspension of registration
12	prohibited acts
17	application of act to imports and exports

CAA

110	State implementation plans
112(c)	hazardous air pollutant - prohibitions

FWPCA

101	declaration of goals and policy
208(b)(2)(K)	areawide waste treatment - disposal of pollutants
308(c)	inspection, monitoring and entry by States
311(b)(1)	policy - no discharges of oil or hazardous substances
402(b)	NPDES permits - State programs

SDWA

FD&CA

301	prohibited acts
603	cosmetics labeling - exemptions
701	general regulation-writing authority
801	imports

OSHA

2(b)	statement of purpose and policy
8(d)	duplicative and excessive burden provisions
18	State jurisdiction and State plans
20(a)(5)	reimbursement of employer's monitoring costs
20(d)	Secretary of HEW - responsibilities assigned to NIOSH

FMS&HA

103(e)	burdensome or duplicative requirements - small business considerations
201	interim standards - coverage

CPSA

12(a)	authority to proceed against an imminent hazard
17	application of the Act to imports
19	prohibited acts

FHSA

3(a)	designation of hazardous substances
4	prohibited acts
10(b)	relevant to subsection 10(a)
14	imports
18	effect upon other Federal and State laws

FFA

4(b)	criteria for a flammability standard
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PPPA

HMTA

101	short title
104	designation of hazardous materials
105(c)	certified containers
301	short title
303	establishment of National Transportation Safety Board

RSA

Title III	Hazardous Materials Transportation Control Act (repealed)
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PUBLIC LAW - 94-469 -- October 11, 1976

"TOXIC SUBSTANCES CONTROL ACT"

FINDINGS, POLICY AND INTENT

SEC. 2.

XVII

(b) Policy. -- It is the policy of the United States that --

(1) adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;...

DEFINITIONS

SEC. 3.

As used in this Act:

XVI

(1) "Administrator" means the Administrator of the Environmental Protection Agency...

XVI

(6) "Health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act...

XVI

(12) "Standards for the development of test data" means prescription of --

(A) the --

(1) health and environmental effects, and

(ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment, for which test data are to be developed and any analysis that is to be performed on such data; and

(B) as necessary to assure that the data are reliable and adequate --

(i) the manner in which such data are to be developed,

(ii) specification of any test protocol or methodology to be employed, and

(iii) other requirements necessary to provide such assurance...

TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

VI SEC. 4.

(a) TESTING REQUIREMENTS. -- If the Administrator finds that --

(1) (A) (i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture is necessary to develop such data; or

(B) (i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it may reasonably be expected to enter the environment in substantial quantities or (II) there may be significant human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing is necessary to develop such data;
and

(2) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule require that testing be conducted on such substance or mixture to develop data with respect to the health and environmental effects for which there is an insufficiency of data and experience and which are relevant to a determination that the ... substance or mixture... does or does not present an unreasonable risk of injury to health or the environment.

(b) (1) Testing Requirement Rule. — A rule under subsection (a) shall include —

(A) identification of the chemical substance or mixture for which testing is required under the rule,

(B) standards for the development of test data for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator data developed in accordance with the standards referred to in subparagraph (B) above.

In determining the standards and period to be included in a rule under subsection (a) above, the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required and the reasonably foreseeable availability of facilities and personnel needed to perform the testing required. Any such rule may require the submission of preliminary data during the testing period.

XV

(2) (A) The health and environmental effects for which standards may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. The characteristics of chemical substances and mixtures for which such standards may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristics which may present such a risk. The methodologies that may be prescribed in such standards include epidemiologic studies, serial or hierarchical tests, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) At least once each 12 months, the Administrator shall review the adequacy of the standards for development of data prescribed in rules under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such standards.

(3) (A) A rule under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) below to conduct tests and submit data to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such data on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit data on a chemical substance or mixture subject to a rule under subsection (a):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator finds that there are insufficient data and experience as described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) above.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator finds that there are insufficient data and experience as described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) above.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator finds that there are insufficient data and experience as described in subsection (a)(1)(A)(ii) or (a)(1)(B)(ii) with respect to the distribution in commerce, use, or disposal of such substance or mixture...

II

(5)... (C) the Administrator shall make and publish with any testing rule the findings described in paragraph (1)(A) or (1)(B) of subsection (a) above and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection ...

XIV

(d) NOTICE. -- Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall publish a notice in the Federal Register within 15 days. Subject to section 14 [disclosure of data] each notice shall (1) identify the chemical substance or mixture; (2) list the uses or intended uses and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. Except as otherwise provided in section 14, such data shall be made available by the Administrator for examination by any person.

IV

(e) PRIORITY LIST. -- (1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the promulgation of a testing rule. In making such a recommendation, the committee shall consider all relevant factors, including --

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of data concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of data upon which the effects of the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a). The committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list for which the Administrator should, within 12 months initiate a proceeding under subsection (a). The number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than September 1, 1977, the committee shall publish the list in the Federal Register together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months the committee shall revise the list and send it to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for the revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file written comments on any new or revised list, and shall make such comments available to the public. Within 12 months after its appearance on the list, the Administrator shall, with respect to any chemical substance or mixture, either initiate a rulemaking proceeding under subsection (a) or publish in the Federal Register his reason for not doing so.

(2) (A) The committee established by paragraph (1)(A) shall consist of eight members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency..

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970.

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce...

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

XVII

(f) REQUIRED ACTIONS. -- Upon the receipt of --

(1) any test data required to be submitted under this Act, or

(2) which indicates that a chemical substance or mixture may present or will present a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the Administrator shall, within 180 days, initiate appropriate action under section 5, 6, or 7 to prevent or reduce such risk or publish in the Federal Register a finding that such risk is not unreasonable. The Administrator may extend such period for an additional period of not more than 90 days. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review. This subsection shall not take effect until January 1, 1979.

X

(g) PETITION FOR STANDARDS FOR THE DEVELOPMENT OF TEST DATA. --

II

A person intending to manufacture or process a chemical substance for which notice is required under section 5(a) and who is not required under a rule under subsection 4(a) above to conduct tests and submit data on such substance may petition the Administrator to prescribe standards for the development of test data for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such standards for such substance.

MANUFACTURING AND PROCESSING NOTICES

XI

SEC. 5.

(a) IN GENERAL. --

(1) Except as provided in subsection (h) [exemptions], no person may --

(A) manufacture a new chemical substance on or after the 30th day after the publication of the inventory required by section 8(b), or

(B) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2) below, is a significant new use,

unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d) below, of such person's intention to

I manufacture or process such substance and such person submits test data in compliance with any applicable requirement of subsection (b) below.

II (2) A determination by the Administrator that a use of a chemical substance is a significant new use shall be made by a rule promulgated after a consideration of all relevant factors, including --

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(b) SUBMISSION OF TEST DATA. --

(1) (A) If a person is required by subsection (a)(1) above to submit a premanufacture notice to the Administrator and is also required to submit test data (pursuant to a rule under section 4) before the submission of notice, he shall submit the test data at the time notice is submitted...

XIII (2) (A) If a person --

(i) is required to submit a notice before beginning manufacture or processing of a chemical substance listed by the Administrator on the list described in paragraph (4) below, and

(ii) is not required by a rule promulgated under section 4 to submit test data for such substance,

then such person shall submit data prescribed by subparagraph (B) below at the time notice is submitted.

(B) Data submitted pursuant to subparagraph (A) above shall be data which the person believes show that --

(i) the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) the intended significant new use chemical substance will not present an unreasonable risk of injury to health or the environment.

XIV

(3) Data submitted under paragraph (b)(1) or (b)(2) above shall be made available, subject to section 14, for examination by interested persons.

II

(4) (A) (i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which he finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment.

(ii) In adding a substance to the list, the Administrator shall consider all relevant factors, including --

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C)... (iii) the Administrator shall make and publish with any rule under this subsection, the finding required in subparagraph (A)...

(d) CONTENT OF NOTICE; PUBLICATIONS IN THE FEDERAL REGISTER --

XII

(1) The notice required by subsection (a) shall include --

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 8(a)(2), and

(B) in such form and manner as the Administrator may prescribe, any test data in the possession or control of the person giving such notice which are related to the

effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

- V (C) a description of any other data concerning the environmental and health effects of such substance insofar as known to the person making the notice or insofar as reasonably ascertainable.

XIV Such a notice shall be made available, subject to section 14, for examination by interested persons.

XIV (2) Subject to section 14, not later than five [business] days after the date of the receipt of a notice or of data the Administrator shall publish in the Federal Register a notice which —

(A) identifies the chemical substance for which notice or data has been received;

(B) lists the uses or intended uses of such substance; and

(C) in the case of the receipt of data describes the nature of the tests performed on such substance and any data developed.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

XIV (3) At the beginning of each month the Administrator shall publish in the Federal Register a list of (A) each chemical substance for which notice has been received under subsection (a) and for which the notification period has not expired, and (B) each chemical substance for which such notification period has expired since the last publication in the Federal Register of such list.

XVII (e) REGULATION PENDING DEVELOPMENT OF INFORMATION. --

(1) (A) If the Administrator determines that -

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); and

(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance, the Administrator may issue a proposed order to take effect on the expiration of the notification period, [or seek a court injunction] to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities, pending development of further information...

XIV

(g) STATEMENT OF REASONS FOR NOT TAKING ACTION. -- If the Administrator has not initiated any action to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, for which notification or data is required before the expiration of the notification period he shall publish a statement of his reasons for not initiating such action. The statement shall be published in the Federal Register before the expiration of such period. Publication in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

X

(h) EXEMPTIONS. --

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) [premanufacture notice] or (b) [submission of data] to permit such person to manufacture or process a chemical substance for test marketing purposes --

(A) upon a showing by such person that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, and

(B) under such restrictions as the Administrator considers appropriate.

(2) (A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit data for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that --

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which data has been submitted to the Administrator as required by subsection 5(b)(2), and

(ii) submission of data by the applicant would be duplicative of data which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit data on the substance...

REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES

XVII SEC. 6.

(a) SCOPE OF REGULATION. -- If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:
...

XV

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection...

XI

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors of such substance or mixture and, to the extent reasonably ascertainable, to other persons

in possession of or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture (as elected by the person to which the requirement is directed).

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

V (b) QUALITY CONTROL. -- If the Administrator has a reasonable basis to conclude that a particular manufacturer or processor is manufacturing or processing a chemical substance or mixture in a manner which unintentionally causes or will cause the chemical substance or mixture to present an unreasonable risk of injury to health or the environment --

(1) the Administrator may by order require such manufacturer or processor to submit a description of the relevant quality control procedures followed in the manufacturing or processing of such chemical substance or mixture; and

(2) if the Administrator determines --

(A) that such quality control procedures are inadequate the Administrator may order revision of the quality control procedures to the extent necessary to remedy such inadequacy; or

XI (B) that such quality control procedures have resulted in distribution of chemical substances or mixtures which present an unreasonable risk of injury to health or the environment, the Administrator may order the manufacturer or processor to (i) give notice of such risk to processors or distributors or both, and, to the extent reasonably ascertainable, to any other person in possession of or exposed to the substance, (ii) to give public notice of such risk, and (iii) to provide such replacement or repurchase of any such substance or mixture as is necessary to adequately protect health or the environment...

II (c) PROMULGATION OF SUBSECTION (a) RULES. --

(1) In promulgating any rule under subsection 6(a) the Administrator shall consider and publish a statement with respect to --

(A) the effects of the substance or mixture on health and the magnitude of human exposure,

(B) the effects of the substance or mixture on the environment and the magnitude of environmental exposure,

(C) the benefits of the substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

III

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection 6(a) unless he finds that it is in the public interest. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury...

IMMINENT HAZARDS

XI

SEC. 7...

(b) RELIEF AUTHORIZED...

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses...

REPORTING AND RETENTION OF INFORMATION

SEC. 8.

(a) Reports. --

VII

(1) The Administrator shall promulgate rules under which --

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than for research) shall maintain such records, and shall submit to the Administrator such reports, as he may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process --

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or research, including research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this Act.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this Act. For purposes of the compilation of the inventory required under subsection 8(b) below, the Administrator shall promulgate rules pursuant to this subsection not later than June 30, 1977.

VI
XII

(2) The Administrator may require under paragraph (1) above maintenance of records and reporting with respect to the following, insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each such substance and mixture manufactured or processed, or reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories

of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing data concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment, and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

XVII To the extent feasible, the Administrator shall not require under paragraph (1) any reporting which is unnecessary or duplicative.

VII (3) (A) (i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as may be required for publication of the first inventory required by subsection (b) below.

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture --

(I) subject to a rule proposed or promulgated under section 4 [testing], 5(b)(4) [list of possible hazards], or 6 [regulation of hazardous substances or mixtures], or an order in effect under section 5(e) [regulation pending development of information], or

(II) with respect to which relief has been granted pursuant to a civil action brought under section 5 or 7 [imminent hazards],

to maintain such records and to submit such reports as he may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2) above.

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

II (b) INVENTORY. --

(1) The Administrator shall compile, keep current, and publish a list [inventory] of each chemical which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports (under section 5 or subsection (a) of this section) is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States [after January 1, 1975]. A chemical substance for which a premanufacture notice is submitted shall be included on the inventory as of the earliest date on which such substance was manufactured or processed. The Administrator shall first publish such a list [inventory] not later than [November 11, 1977]. The Administrator shall not include any chemical substance manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research.

(2) To the extent consistent with the purposes of this Act, the Administrator may, in lieu of listing a chemical substance individually, list a category of chemical substances in which the substance is included.

VI (c) RECORDS. -- Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

VIII
XIII

XII (d) HEALTH AND SAFETY STUDIES. -- The Administrator shall promulgate rules under which he shall require any person who manufactures, processes, or distributes in commerce any chemical substance or mixture (or with respect to paragraph (2) below, any person who has possession of a study) to submit to the Administrator --

(1) lists of health and safety studies with respect to such substance or mixture (A) conducted or initiated by or for such person at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if he finds that submission of lists of such studies is unnecessary to carry out the purposes of this Act, and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) above, or otherwise known by such person.

XI (e) NOTICE TO ADMINISTRATOR OF SUBSTANTIAL RISKS. -- Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed.

RELATIONSHIP TO OTHER FEDERAL LAWS

III SEC. 9.

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR. --

(1) If the Administrator concludes that any activity or combination of activities will present an unreasonable risk of injury to health or the environment and that the risk may be prevented or reduced sufficiently by another agency, he shall submit to that agency a report which describes the activity he believes presents a risk. The report shall also request the agency --

(A) (i) to determine if the risk may be prevented or reduced sufficiently by the agency, and

(ii) if the agency determines that such risk may be prevented or reduced, to issue an order declaring whether or not the activity or combination of activities indeed presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

II Any report of the Administrator shall include a detailed statement of the information on which it is based and be published in the Federal Register. The agency receiving a request shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies but not in less than 90 days. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions shall be published in the Federal Register...

II (3) If the Administrator initiates action under section 6 or 7 against a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall, before taking any action of its own, consult with the Administrator for the purpose of avoiding duplication of Federal action.

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR. -- The Administrator shall coordinate his actions under this Act with his actions under other Federal laws. If he determines that a risk to health or the environment would be eliminated or reduced sufficiently by actions under other Federal laws, the Administrator shall use such authorities unless he determines it is in the public interest to protect against such risk by actions under this Act...

(d) COORDINATION. -- In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health, Education, and Welfare and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements...

RESEARCH, DEVELOPMENT, COLLECTION, DISSEMINATION, AND UTILIZATION OF DATA

II SEC. 10.
III

V (a) AUTHORITY. -- The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and with other appropriate departments and agencies, conduct such research, development, and monitoring as is necessary to carry out the purposes of this Act. The Administrator may enter into contracts and may make grants for research, development, and monitoring under this subsection...

(b) DATA SYSTEMS. --

III (1) The Administrator shall establish, administer, and be responsible for the continuing activities of an interagency committee which shall design, establish, and coordinate an efficient and effective system, within the Environmental Protection Agency, for the collection, dissemination to other Federal departments and agencies, and use of data submitted under this Act.

(2) (A) The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare and other appropriate departments and agencies, design, establish, and coordinate an efficient and effective system for the retrieval of toxicological and other scientific data which could be useful to the Administrator in carrying out the purposes of this Act. Systematized retrieval shall be developed for use by all Federal and other departments and agencies with responsibilities in the area of regulation or study of chemical substances and mixtures and their effect on health or the environment...

(c) SCREENING TECHNIQUES. -- The Administrator shall, with the Assistant Secretary for Health of the Department of Health, Education, and Welfare, undertake research directed toward the development of rapid, reliable, and economical screening techniques for carcinogenic, mutagenic, teratogenic, and ecological effects of chemical substances and mixtures.

(d) MONITORING. -- The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish and be responsible for research aimed at the development of monitoring techniques and instruments which may be used in the detection of toxic chemical substances and mixtures and which are reliable, economical, and capable of being implemented under a wide variety of conditions.

(e) BASIC RESEARCH. -- The Administrator shall, in consultation and cooperation with the Secretary of Health, Education, and Welfare, establish research programs to develop the fundamental scientific basis of the screening and monitoring techniques described in subsections (c) and (d) above, the bounds of the reliability of such techniques, and the opportunities for their improvement...

II (g) EXCHANGE OF RESEARCH AND DEVELOPMENT RESULTS. -- The Administrator shall, in consultation with the Secretary of Health, Education, and Welfare and other appropriate departments and agencies, establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures.

INSPECTIONS AND SUBPOENAS

SEC. 11.

VIII (a) IN GENERAL. -- For purposes of administering this Act, the Administrator, and any duly designated representative of the

Administrator, may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, or such articles in connection with distribution in commerce. Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice. Each inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

(b) SCOPE. --

(1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this Act applicable to the chemical substances or mixtures within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to --

(A) financial data,

(B) sales data (other than shipment data),

(C) pricing data,

(D) personnel data, or

(E) research data (other than data required by this Act or under a rule promulgated thereunder),

unless the nature and extent of such data are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

IX

(c) SUBPOENAS. -- In carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary...

EXPORTS

XVII

SEC. 12.

(a) IN GENERAL. --

(1) Except as provided in paragraph (2) and subsection (b) below, this Act (other than section 8) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if --

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed, bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that it will present an unreasonable risk of injury to health or the environment in the United States. The Administrator may require, under section 4, testing of any chemical substance or mixture exempted from this Act by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health or the environment in the United States.

XI

(b) NOTICE. --

(1) If any person exports or intends to export a chemical substance or mixture for which the submission of data is required under section 4 [testing] or 5(b) [list of possible hazards], such person shall notify the Administrator of such exportation or intent and the Administrator shall furnish to the government of such country notice of the availability of the data submitted.

(2) If any person exports or intends to export a chemical substance or mixture for which an order has been issued under section 5 or a rule has been proposed or promulgated under section 5 [premanufacture notices] or 6 [regulation of hazardous substances] or with respect to which an action is pending, or relief has been granted under section 5 [regulation pending development of information and protection against unreasonable risk] or 7 [imminent hazards], such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.

ENTRY INTO CUSTOMS TERRITORY OF THE UNITED STATES

XVII SEC. 13.

(a) IN GENERAL. --

(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if --

(A) it fails to comply with any rule in effect under this Act, or

(B) it is offered for entry in violation of section 5 or 6, a rule or order under section 5 or 6, or an order issued in a civil action brought under section 5 or 7...

DISCLOSURE OF DATA

XIV SEC. 14.

(a) IN GENERAL. -- Except as provided by subsection (b) below, any information otherwise obtained by the Administrator which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of such section shall not be disclosed except that such information --

(1) shall be disclosed to any officer or employee of the United States --

(A) in connection with the official duties of such employee under any law for the protection of health or the environment, or

(B) for specific law enforcement purposes;

(2) shall be disclosed to contractors with the United States and employees of such contractors if such disclosure is necessary and under such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines it necessary to protect health or the environment; or

(4) may be disclosed when relevant in any proceeding under this Act, except that disclosure shall be made in such manner as to preserve confidentiality.

In any proceeding under section 552(a) of title 5, United States Code, to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

(b) DATA FROM HEALTH AND SAFETY STUDIES. --

(1) Subsection (a) does not prohibit the disclosure of --

(A) any health and safety study which is submitted under this Act with respect to --

(i) any chemical substance or mixture which has been offered for commercial distribution, or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5, and

(B) any data obtained by the Administrator from a health and safety study which relates to such a chemical substance or mixture.

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

(2) If a request is made to the Administrator under subsection (a) of section 552 of title 5, United States Code, for health and safety study information described above (which is not process or formulation information as described above) the Administrator may not deny such request on the basis of subsection (b)(4) of section 552 of title 5, U.S.C.

(c) DESIGNATION AND RELEASE OF CONFIDENTIAL DATA. —

(1) In submitting data under this Act, a manufacturer, processor, or distributor in commerce may designate the data which he believes is entitled to confidential treatment under subsection (a), and submit such data separately from other data. A designation under this paragraph shall be made in writing in such manner as the Administrator prescribes.

(2) (A) Except as provided by subparagraph (B) below, if the Administrator proposed to release for inspection data which has been designated confidential, he shall notify, by certified mail, the manufacturer, processor, or distributor in commerce who submitted such data of his intent to release it. If the release is to be made pursuant to a request under section 552(a) of title 5, United States Code, the required notice shall be given immediately upon approval of such request. The Administrator may not release such data until the expiration of 30 days after the manufacturer, processor, or distributor in commerce has received the required notice.

(B) (i) Subparagraph (A) above, requiring notices prior to release of information, shall not apply to the release of information under paragraph (1), (2), (3), or (4) of subsection (a) above, except that the

Administrator may not release data under paragraph (3) of subsection (a) unless he has notified each manufacturer, processor, and distributor in commerce who submitted the data of the release. Such notice shall be made by certified mail at least 15 days before the release. If the Administrator determines that the release of data is necessary to protect against an imminent, unreasonable risk of injury to health or the environment, such notice may be made by such means as he determines will provide notice at least 24 hours before such release is made.

(ii) Subparagraph (A) shall not apply to the release of information in health and safety studies as described in subsection (b)(1) other than process and formulation information described in the second sentence of that subsection...

* * *

STUDIES

II SEC. 25.

(b) CLASSIFICATION, STORAGE, AND RETRIEVAL STUDY. -- The Council on Environmental Quality, in consultation with the Administrator, the Secretary of Health, Education, and Welfare, the Secretary of Commerce, and the heads of other appropriate Federal departments or agencies, shall coordinate a study of the feasibility of establishing (1) a standard classification system for chemical substances and related substances, and (2) a standard means for storing and for obtaining rapid access to information respecting such substances. A report on such study shall be completed and submitted to Congress not later than [July 1, 1977].

ADMINISTRATION OF THE ACT

SEC. 26.

III

(a) COOPERATION OF FEDERAL AGENCIES. -- Upon request by the Administrator, each Federal Department and agency is authorized --

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this Act; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this Act...

XVI

(c) ACTION WITH RESPECT TO CATEGORIES. --

(1) Any action authorized or required to be taken by the Administrator under any provisions of this Act with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this Act with respect to a category of chemical substances or mixtures, any reference in this Act to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term "category of chemical substances" means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term "category of mixtures" means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this Act...

(f) STATEMENT OF BASIS AND PURPOSE. -- Any final order issued under this Act shall be accompanied by a statement of its basis and purpose. The contents and adequacy of such statements shall not be subject to judicial review in any respect...

DEVELOPMENT AND EVALUATION OF TEST METHODS

SEC. 27.

III

(a) IN GENERAL. -- The Secretary of Health, Education and Welfare, in consultation with the Administrator and acting through the Assistant Secretary for Health, may conduct, and make grants to public and nonprofit private entities and enter into contracts with public and private entities for, projects for the development and evaluation of

inexpensive and efficient methods (1) for determining and evaluating the health and environmental effects of chemical substances and mixtures, and their toxicity, persistence, and other characteristics which affect health and the environment, and (2) which may be used for the development of test data to meet the requirements of rules promulgated under section 4. The Administrator shall consider such methods in prescribing under section 4 standards for the development of test data...

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I SEC. 30.

The Administrator shall submit to the President and Congress each January 1, a report including --

(1) a list of the testing required under section 4 during the year and an estimate of the costs imposed by such testing requirement...

PUBLIC LAW 94-580 -- October 21, 1976

"RESOURCE CONSERVATION AND RECOVERY ACT OF 1976"

SUBTITLE A -- GENERAL PROVISIONS

* * *

DEFINITIONS

SEC. 1004.

As used in this Act: ...

- XVI (1) "Administrator" means the Administrator of the Environmental Protection Agency...
- XVI (3) "Disposal" means the discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste into or on any land or water so that such solid waste or hazardous waste or any constituent thereof may enter the environment or be emitted into the air or discharged into any waters, including ground waters...
- XVI (5) "Hazardous waste" means a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may --
- (A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible illness, or;
- (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed...
- XVI (12) "Manifest" means the form used for identifying the quantity, composition, and the origin, routing, and destination of hazardous waste during its transportation from the point of generation to the point of disposal, treatment, or storage...
- XVI (27) "Solid waste" means any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semisolid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations,

and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended (86 Stat. 880), or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (68 Stat. 923)...

XVI (33) "Storage", when used in connection with hazardous waste, means the containment of hazardous waste, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal of such hazardous waste.

XVI (34) "Treatment", when used in connection with hazardous waste, means any method, technique, or process, including neutralization, designed to change the physical, chemical, or biological character or composition of any hazardous waste so as to neutralize such waste or so as to render such waste nonhazardous, safe for transport, amenable for recovery, amenable for storage, or reduced in volume. Such term includes any activity or processing designed to change the physical form or chemical composition of hazardous waste so as to render it nonhazardous...

* * *

APPLICATION OF ACT AND INTEGRATION WITH OTHER ACTS

III SEC. 1006...

(b) INTEGRATION WITH OTHER ACTS. — The Administrator shall integrate all provisions of this Act and shall avoid duplication, to the maximum extent practicable, with the appropriate provisions of the Clean Air Act, the Federal Water Pollution Control Act, the Federal Insecticide, Fungicide, and Rodenticide Act, the Safe Drinking Water Act, the Marine Protection, Research and Sanctuaries Act of 1972 and such other Acts of Congress as grant regulatory authority to the Administrator. Such integration shall be effected only to the extent that it can be done in a manner consistent with the goals and policies expressed in this Act and in the other acts.

* * *

SOLID WASTE MANAGEMENT INFORMATION AND GUIDELINES

SEC. 1008.

II (a) GUIDELINES. — By October 21, 1977, the Administrator shall, in cooperation with appropriate Federal, State, municipal, and intermunicipal

agencies, and in consultation with other interested persons, and after public hearings, develop and publish suggested guidelines for solid waste management. Such suggested guidelines shall --

(1) provide a technical and economic description of the level of performance that can be attained by various available solid waste management practices (including operating practices) which provide for the protection of public health and the environment;

(2) not later than October 21, 1978, describe levels of performance, including appropriate methods and degrees of control, that provide at a minimum for (A) protection of public health and welfare; (B) protection of the quality of ground waters and surface waters from leachates; (C) protection of the quality of surface waters from runoff through compliance with effluent limitations under the Federal Water Pollution Control Act, as amended; (D) protection of ambient air quality through compliance with new source performance standards or requirements of air quality implementation plans under the Clean Air Act, as amended; (E) disease and vector control; (F) safety; and (G) esthetics; and

(3) provide minimum criteria to be used by the States to define those solid waste management practices which constitute the open dumping of solid waste or hazardous waste and are to be prohibited under title IV of this Act.

Where appropriate, such suggested guidelines also shall include minimum information for use in deciding the adequate location, design, and construction of facilities associated with solid waste management practices including the consideration of regional geographic, demographic and climatic factors.

SUBTITLE B -- OFFICE OF SOLID WASTE; AUTHORITIES
OF THE ADMINISTRATOR

* * *

AUTHORITIES OF THE ADMINISTRATOR

SEC. 2002.

(a) AUTHORITIES. -- In carrying out this Act, The Administrator is authorized to --

VII

(1) prescribe, in consultation with Federal, State, and regional authorities, such regulations as are necessary to carry out his functions under this Act; ...

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SUBTITLE C -- HAZARDOUS WASTE MANAGEMENT

IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

SEC. 3001.

- II (a) CRITERIA FOR IDENTIFICATION OR LISTING. -- Not later than March 21, 1978, the Administrator shall, after notice and opportunity for public hearing, and after consultation with appropriate Federal and State agencies, develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, which should be subject to the provisions of this subtitle, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics. Such criteria shall be revised from time to time as may be appropriate.
- II (b) IDENTIFICATION AND LISTING. -- Not later than April 22, 1978, the Administrator shall promulgate regulations identifying the characteristics of hazardous waste, and listing particular hazardous wastes...

STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

II SEC. 3002.

Not later than April 22, 1978, the Administrator shall promulgate regulations establishing standards applicable to generators of hazardous waste. Such standards shall establish requirements respecting --

- VI (1) record-keeping to accurately identify the quantities of such hazardous waste generated, the significant constituents thereof and the disposition of such wastes;
- XV (2) labeling for containers used for storage, transport, or disposal of hazardous waste that accurately identifies such waste;...
- XI (4) furnishing information on the chemical composition to persons transporting, treating, storing, or disposing of such wastes;
- VI (5) use of a manifest system to assure that all such hazardous waste is designated for treatment, storage, or disposal in facilities for which a permit has been issued; and

XII (6) submission of reports to the Administrator (or the State agency authorized to carry out the permit program) setting out --

(A) the quantities of hazardous waste that he has generated during a particular time period; and

(B) the disposition of that hazardous waste.

STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

SEC. 3003.

II (a) STANDARDS. -- Not later than April 22, 1978, the Administrator,
III after consultation with the Secretary of Transportation shall promulgate regulations establishing standards, applicable to transporters of hazardous waste. Such standards shall include requirements respecting --

XII (1) record-keeping concerning such hazardous waste transported, and their source and delivery points;

XV (2) transportation of such waste only if properly labeled;

VI (3) compliance with the manifest system referred to in section 3002(5); and

XVI (4) transportation of all such hazardous waste only to the hazardous waste facilities which the shipper designates on the manifest form to be a permit-holding facility.

(b) COORDINATION. -- In all regulations under this Act, the Administrator will consult and coordinate with the regulations and activities of the Secretary of Transportation under the Hazardous Materials Transportation Act.

STANDARDS APPLICABLE TO OWNERS AND OPERATORS
OF HAZARDOUS WASTE TREATMENT, STORAGE,
AND DISPOSAL FACILITIES

II SEC. 3004.

Not later than April 22, 1978, the Administrator shall promulgate regulations establishing performance standards applicable to owners and operators of facilities for the treatment, storage, or disposal of hazardous waste. Such standards shall include requirements respecting --

- VI (1) maintaining records of all hazardous wastes treated, stored, or disposed of and the manner in which this was done;
- III V VI (2) satisfactory reporting, monitoring, and inspection
XII and compliance with the manifest system referred to in section 3002(5);...
- X (7) compliance with the requirements of section 3005 respecting permits for treatment, storage, or disposal.

PERMITS FOR TREATMENT, STORAGE OR DISPOSAL
OF HAZARDOUS WASTE

X SEC. 3005.

(a) PERMIT REQUIREMENTS. -- Not later than April 22, 1978, the Administrator shall promulgate regulations requiring each person owning or operating a facility for the treatment, storage, or disposal of hazardous waste to have a permit issued pursuant to this section. Ninety days after the Administrator has published the subsection 3001(b) list of hazardous wastes, the disposal of any such waste is prohibited except in accordance with such a permit.

XII (b) REQUIREMENTS OF PERMIT APPLICATION. -- Each application for a permit shall contain such information as may be required under regulations promulgated by the Administrator, including information respecting ----

(1) estimates of the composition, quantities, and concentrations of any hazardous waste proposed to be disposed of, treated, transported, or stored, and the time, frequency, or rate at which such waste is proposed to be disposed of, treated, transported, or stored; and

(2) the site at which such hazardous waste will be disposed of, treated, transported to, or stored.

* * *

INSPECTIONS

VIII SEC. 3007.

(a) ACCESS ENTRY. -- For purposes of developing any regulation or enforcing the provisions of this subtitle, any person who generates, stores, treats, transports, disposes of, or otherwise handles hazardous

XIII wastes shall, upon request of any officer designated by the Administrator, or any designated officer of a State having an authorized hazardous waste program, furnish or permit such officer at all reasonable times to have access to, and to copy all records relating to such wastes. Such officers are authorized --

(1) to enter at reasonable times any establishment where hazardous wastes are generated, stored, treated, or disposed of;

(2) to inspect and obtain samples of any such wastes and samples of any containers or labeling for such wastes.

XIV (b) AVAILABILITY TO PUBLIC. -- Any records, reports, or information obtained from any person under this section shall be available to the public, except that upon a showing that such records, reports, or information, are entitled to protection under section 1905 of Title 18 of the United States Code, the Administrator shall consider such information confidential in accordance with the purposes of that section, except that such record, report, document, or information may be disclosed to other officers, of the United States concerned with carrying out this Act, or when relevant in any proceeding under this Act.

ENFORCEMENT

XVII SEC. 3008.

(a) COMPLIANCE ORDERS. -- Whenever, on the basis of any information, the Administrator determines that any person is in violation of any requirement of this subtitle, he shall give notice to the violator. If such violation extends beyond the thirtieth day after notification, the Administrator may issue an order requiring compliance within a specified time period...

(3) If such violator fails to take corrective action within the time specified in the order, the Administrator may suspend or revoke any permit issued to the violator.

IV (b) PUBLIC HEARING. -- Any order or any suspension or revocation of a permit shall become final unless the person named therein requests a public hearing. Upon such request the Administrator shall promptly conduct a public hearing. In connection with and proceeding under this section, the Administrator may issue subpoenas for the attendance and IX testimony of witnesses and the production of relevant papers, books, and documents, and may promulgate rules for discovery procedures.

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EFFECTIVE DATE

SEC. 3010.

X XI

(a) PRELIMINARY NOTIFICATION. -- Not later than ninety days after promulgation of regulations under section 3001 identifying or listing any substance as hazardous waste any person generating or transporting such substance or owning or operating a facility for treatment, storage, or disposal of such substance shall file with the Administrator a notification stating the location and general description of such activity and the identified or listed hazardous wastes handled. Not more than one such notification shall be required with respect to the same substance. No identified or listed hazardous waste may be transported, treated, stored, or disposed of unless notification has been given under this subsection...

SUBTITLE D -- STATE OR REGIONAL SOLID WASTE PLANS

[Subtitle D contains requirements for the Administrator to develop criteria to assist states in developing solid waste management plans. However, this subtitle is not, in general, applicable to developing or disseminating information on toxic substances and is, therefore, omitted.]

* * *

SUBTITLE F -- FEDERAL RESPONSIBILITIES

* * *

COOPERATION WITH ENVIRONMENTAL PROTECTION AGENCY

III SEC. 6003.

All Federal agencies having functions relating to solid waste or hazardous waste shall cooperate to the maximum extent permitted by law with the Administrator in carrying out his functions under this Act and shall make all appropriate information, facilities, personnel, and other resources available, on a reimbursable basis, to the Administrator upon his request.

* * *

SUBTITLE H -- RESEARCH, DEVELOPMENT, DEMONSTRATION,
AND INFORMATION

RESEARCH, DEMONSTRATION, TRAINING, AND
OTHER ACTIVITIES

II SEC. 8001.

III (a) GENERAL AUTHORITY. -- The Administrator, alone or after consultation with the Administrator of the Federal Energy Administration, the Administrator of the Energy Research and Development Administration, or the Chairman of the Federal Power Commission, shall conduct, encourage, coordinate, cooperate with, and render financial and other assistance to appropriate public and private agencies and institutions, and individuals in the conduct of research, investigations, experiments, training, demonstrations, surveys, public education programs, and studies relating to --

(1) any adverse health and welfare effects of the release into the environment of material present in solid waste, and methods to eliminate such effects;...

(5) the reduction of the amount of such waste and unsalvageable waste materials; ...

(10) improvements in land disposal practices for solid waste (including sludge) which may reduce the adverse environmental effects of such disposal and other aspects of solid waste disposal on land, including means for reducing the harmful environmental effects of earlier and existing landfills, means for rendering landfills safe for purposes of construction and other uses, and techniques of recovering materials and energy from landfills; ...

(12) methods of hazardous waste management, including methods of rendering such waste environmentally safe; and

(13) any adverse effects on air quality (particularly with regard to the emission of heavy metals) which result from solid waste which is burned (either alone or in conjunction with other substances) for purposes of disposal or energy recovery.

III (b) MANAGEMENT PROGRAM. --

(1) (A) In carrying out his functions pursuant to this Act, and any other Federal legislation respecting solid waste or discarded material research, development, and demonstrations, the Administrator shall establish a management program or system to insure the coordination of all such activities and to facilitate and accelerate the process of development of sound new technology (or other discoveries) from the research phase, through development, and into the demonstration phase.

SPECIAL STUDIES; PLANS FOR RESEARCH, DEVELOPMENT,
AND DEMONSTRATIONS

II SEC. 8002...

(b) COMPOSITION OF WASTE STREAM. -- The Administrator shall undertake a systematic study of the composition of the solid waste stream and of anticipated future changes in the composition of such stream and shall publish a report containing the results of such study and quantitatively evaluating the potential utility of such components...

III (f) MINING WASTE. -- The Administrator, in consultation with the Secretary of the Interior, shall conduct a detailed and comprehensive study on the adverse effects on the environment, of solid waste from mines including effects on humans, water, air, health, welfare, and natural resources, and on means currently employed to dispose of and utilize such solid wastes and to prevent or substantially mitigate such adverse effects. Such study shall include an analysis of --

(1) the sources and volume of discarded material generated per year from mining;

(2) present disposal practices;

(3) potential dangers to human health and the environment from surface runoff of leachate and air pollution by dust;

(4) alternatives to current disposal methods;

(5) the cost of those alternatives in terms of the impact on mine product costs; and

(6) potential for use of discarded material as a secondary source of the mine product.

The Administrator shall publish a report and shall include findings and recommendations.

(g) SLUDGE. -- The Administrator shall undertake a comprehensive study on sludge. Such study shall include an analysis of --

- (1) types of solid waste to be classified as sludge;
- (2) effects of air and water pollution legislation on the creation of sludge;
- (3) amounts of sludge originating in each State and in each industry producing sludge;
- (4) methods of disposal, including cost, efficiency, and effectiveness of such methods;
- (5) alternative methods for the use of sludge, including agricultural applications of sludge and energy recovery from sludge; and
- (6) methods to reclaim sludge disposal or sludge-damaged areas.

II (1) COMPLETION OF RESEARCH AND STUDIES. -- The Administrator shall complete the research and studies, and submit the reports, required under subsections (b), (c), (d), (e), (f), (g), and (k) not later than October 1, 1978. He shall complete the research and studies, and submit the reports, required under subsections (a), (h), (i), and (j) not later than October 1, 1979. Upon completion of each study the Administrator shall prepare a plan for research, development, and demonstration respecting the findings of the study and shall submit any legislative recommendations resulting from such study to Congress.

COORDINATION, COLLECTION, AND DISSEMINATION
OF INFORMATION

II SEC. 8003.

(a) INFORMATION. -- The Administrator shall develop, collect, evaluate, and coordinate information on -- ...

(6) hazardous solid waste, including incidents of damage resulting from the disposal of hazardous solid wastes; inherently and potentially hazardous solid wastes; methods of neutralizing or properly disposing of hazardous solid wastes; facilities that properly dispose of hazardous wastes;...

(b) LIBRARY. --

(1) The Administrator shall establish a central reference library for materials collected pursuant to subsection (a) above ... and other data and information with respect to -- ...

(iii) the various systems and technologies for collection, transport, storage, treatment, and final disposition of solid waste, and

(iv) other aspects of solid waste and hazardous solid waste management.

Such central reference library shall also contain ... subject to any confidentiality requirements, information respecting any aspect of solid waste provided by employees of EPA which may be of value to Federal, State, and local authorities and other persons.

(2) Information in the central reference library shall, to the extent practicable, be collated, analyzed, verified, and published and shall be made available to State and local governments and other persons at reasonable times and subject to such reasonable charges as may be necessary to defray expenses of making such information available.

XIV

(e) INFORMATION PROGRAMS. --

(1) The Administrator shall implement a program for the rapid dissemination of information on ... hazardous waste management ... including the results of any relevant research, investigations, experiments, surveys, studies or other information which may be useful in the implementation of new or improved solid waste management practices and methods and information on any other technical, managerial, financial, or market aspect of resource conservation and recovery facilities...

III

(f) COORDINATION. -- In collecting and disseminating information under this section, the Administrator shall coordinate his actions and cooperate to the maximum extent possible with State and local authorities...

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PUBLIC LAW 92-516 — October 21, 1972

"THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT"

* * *

SEC. 2. DEFINITIONS.

For purposes of this Act — ...

XVI

(e) CERTIFIED APPLICATOR, ETC.

(1) Certified Applicator.— "Certified applicator" means any individual who is certified to use or supervise the use of any pesticide which is classified for restricted use.

XVI

(2) Private Applicator.— "Private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

XVI

(3) Commercial Applicator. — "Commercial applicator" means a certified applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by paragraph (2)...

XVI

(n) INGREDIENT STATEMENT. — "Ingredient statement" means a statement which contains —

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide; and

(2) if the pesticide contains arsenic, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic...

(p) LABEL AND LABELING.—

XVI

(1) Label. — "Label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

XVI

(2) Labeling. -- "Labeling" means all labels and all other written, printed, or graphic matter --

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device.

XVI

(q) MISBRANDED.--

(1) A pesticide is misbranded if --

(A) its labeling bears any statement, design, or graphic representation which is false or misleading;

(B) it is contained in a package which does not conform to the standards established by the Administrator pursuant to section 25(c)(3) [pesticide packaging];

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 7 to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirement imposed under section 3(d) of this Act, is adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environment.

(2) A pesticide is misbranded if --

(A) the label does not bear an ingredient statement on that part of the immediate container which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if:

(i) the size or form of the immediate container, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, a label bearing --

(i) the name and address of the producer, registrant, or person for whom produced;

(ii) the name, brand, or trademark under which the pesticide is sold;

(iii) the net weight or measure of the content: Provided, that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this Act, the registration number assigned to the pesticide under this Act, and the use classification; and

(D) the pesticide contains any substances or substances in quantities highly toxic to man, unless the label bears, in addition to any other matter required by this Act --

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide...

XVI (x) PROTECT HEALTH AND THE ENVIRONMENT. -- "Protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment...

XVI (bb) UNREASONABLE ADVERSE EFFECTS ON THE ENVIRONMENT. -- "Unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide...

X SEC. 3. REGISTRATION OF PESTICIDES.

(a) REQUIREMENT. -- Except as otherwise provided by this Act, no person in any State may distribute, sell, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator...

(c) PROCEDURES FOR REGISTRATION. --

(1) Statement Required. -- Each applicant for registration of a pesticide shall submit to the Administrator a statement which includes --

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

XV (C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;

I (D) if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based...;

(E) the complete formula of the pesticide; and

(F) a request that the pesticide be classified for general use, for restricted use, or for both.

XII (2) Data In Support Of Registration. -- The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information, he shall permit sufficient time for applicants to obtain such additional information. Except as provided by subparagraph (c)(1)(D) above and

section 10 below [confidentiality], within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision...

(5) Approval of Registration. -- The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d) --

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

(6) Denial Of Registration. -- If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, he shall notify the applicant for registration of his determination and of his reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator during the 30-day period beginning the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide...

(d) CLASSIFICATION OF PESTICIDES. --

(1) Classification For General Use, Restricted Use, Or Both. --

(A) As part of the registration of a pesticide, the Administrator shall classify it as being for general use or for restricted use, provided that if the Administrator determines that some of the uses for which it is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses: Provided, however, that the Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

* * *

X SEC. 4. USE OF RESTRICTED USE PESTICIDES; CERTIFIED APPLICATORS.

(a) CERTIFICATION PROCEDURE. --

(1) Federal Certification. -- Subject to paragraph (2) below, the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification: Provided, however, that the certification standard for a private applicator shall be deemed fulfilled by his completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to a requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by him.

(2) State Certification. -- If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose...

X SEC. 5. EXPERIMENTAL USE PERMITS.

(a) ISSUANCE. -- Any person may apply to the Administrator for an experimental use permit for a pesticide. The Administrator may issue an experimental use permit if he determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 3. An application for an experimental use permit may be filed at the time of or before or after an application for registration is filed.

(b) TEMPORARY TOLERANCE LEVEL. -- If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or fuel, he may establish a temporary tolerance level for the residue of the pesticide before issuing an experimental use permit.

(c) USE UNDER PERMIT. -- Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

I
XII

(d) STUDIES. -- When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies shall be reported to the Administrator before such pesticide may be registered under section 3...

(f) STATE ISSUANCE OF PERMITS. -- Notwithstanding the foregoing provisions of this section, the Administrator may, under such terms and conditions as he may by regulation prescribe, authorize any State to issue an experimental use permit for a pesticide.

XVII SEC. 6. ADMINISTRATIVE REVIEW; SUSPENSION.

(a) CANCELLATION AFTER FIVE YEARS. -- ...

(2) Information. -- If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, he shall submit such information to the Administrator.

(b) CANCELLATION AND CHANGE IN CLASSIFICATION. -- If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of his intent either --

(1) to cancel its registration or to change its classification together with the reasons (including factual basis) for his action, or

(2) to hold a hearing to determine whether or not its registration should be cancelled or its classification changed.

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At least 60 days before publishing such notice the Administrator shall provide the Secretary of Agriculture a copy of the notice along with an analysis of any impact on the agricultural economy. If the Secretary comments, the Administrator must publish those comments along with his response in the Federal Register ...

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In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the impact of

such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and he shall publish in the Federal Register an analysis of such impact.

IV (c) SUSPENSION. —

(1) Order. — ...

Except in the case of emergency orders, the Administrator shall notify the registrant prior to issuing a suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity for an expedited hearing ...

- IV (d) PUBLIC HEARINGS AND SCIENTIFIC REVIEW. -- In the event a hearing is requested pursuant to subsection (b) above or determined upon by the Administrator, such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpoena to compel testimony or production of documents from any person...

- IV ...Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record.

X SEC. 7. REGISTRATION OF ESTABLISHMENTS.

(a) REQUIREMENT. — No person shall produce any pesticide subject to this Act unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) REGISTRATION. — Whenever the Administrator receives an application under subsection (a), he shall register the establishment and assign it an establishment number.

XII (c) INFORMATION REQUIRED. —

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides --

(A) which he is currently producing;

(B) which he has produced during the past year; and

(C) which he has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.

XIII (2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 13, inform him of the name and address of any recipient of any pesticide produced in any registered establishment which he operates.

XIV (d) CONFIDENTIAL RECORDS AND INFORMATION. -- Any information submitted to the Administrator pursuant to subsection (c) shall be considered confidential and shall be subject to the provisions of section 10.

SEC. 8. BOOKS AND RECORDS.

VII (a) REQUIREMENTS. -- The Administrator may prescribe regulations requiring producers to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act. No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

VIII (b) INSPECTION. -- For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or delivers any pesticide or device subject to this Act, shall, upon request of any officer of the Environmental Protection Agency or of any State or political subdivision designated by the Administrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information

referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

VIII SEC. 9. INSPECTION OF ESTABLISHMENTS, ETC.

(a) IN GENERAL. -- For purposes of enforcing the provisions of this Act, officers of EPA are authorized to enter at reasonable times, any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices.

... If the officer obtains any samples, prior to leaving the premises, he shall give the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(b) WARRANTS. -- For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by the Administrator are empowered to obtain and to execute warrants authorizing --

(1) entry for the purpose of this section;

(2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device...

XIV SEC. 10. PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) IN GENERAL. -- In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information, and (2) submit such marked material separately from other material required to be submitted under this Act.

(b) DISCLOSURE. -- Notwithstanding any other provision of this Act, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

(c) DISPUTES. -- If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), he shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).

SEC. 11. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

XII (a) IN GENERAL. -- No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

XVII SEC. 12. UNLAWFUL ACTS.

(a) IN GENERAL. --

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person --

(A) any pesticide which is not registered under section 3, except as provided by subsection 6(a)(1);

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration ...;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration...;

XIV

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 25(c)(5);

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person --

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act;

(B) to refuse to keep any records required pursuant to section 8, or to refuse to allow the inspection of any records or establishment pursuant to section 8 or 9, or to refuse to allow an officer or employee of the Environmental Protection Agency to take a sample of any pesticide pursuant to section 9...; ...

(D) to use for his own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this Act which is confidential under this Act;

(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this Act for restricted use without giving the classification of the product assigned to it under section 3;

(F) to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder;

(G) to use any registered pesticide in a manner inconsistent with its labeling;

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any stop sale, stop use, removal or seizure order issued by the Administrator under section 13;

(J) to violate any suspension order issued under section 6;

(K) to violate any cancellation of registration of a pesticide under section 6, except as provided by section 6(a)(1);

(L) who is a producer to violate any of the provisions of section 7 [registration of establishments];

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to section 8, any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this Act;

(O) to add any substance to, or take a substance from, any pesticide in a manner that may defeat the purpose of this Act; or

XI

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test.

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XVII SEC. 17. IMPORTS AND EXPORTS

(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT. -- Notwithstanding any other provision of this Act, no pesticide or device shall be deemed in violation of this Act when intended solely for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices shall be subject to section 8 of this Act (regarding keeping records and books and inspections)...

XI

(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS. -- Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies.

(c) IMPORTATION OF PESTICIDES AND DEVICES. -- The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony.

III (d) COOPERATION IN INTERNATIONAL EFFORTS. -- The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

(e) REGULATIONS. -- The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) above.

* * *

II SEC. 20. RESEARCH AND MONITORING.

(a) RESEARCH. -- The Administrator shall undertake research, including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this Act, and he shall give priority to research to develop biologically integrated alternatives for pest control. The Administrator shall also take care to insure that such research does not duplicate research being undertaken by any other Federal agency.

(b) NATIONAL MONITORING PLAN. -- The Administrator shall formulate and periodically revise, in cooperation with other Federal, State, or local agencies, a national plan for monitoring pesticides.

V (c) MONITORING. -- The Administrator shall undertake such monitoring activities, including but not limited to monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this Act and of the national pesticide monitoring plan. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.

SEC. 21. SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

III (a) The Administrator, before publishing regulations under this Act, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 25(a) below.

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SEC. 25. AUTHORITY OF ADMINISTRATOR.

- VII (a) (1) REGULATIONS. — The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides...
- III (2) Prior to publishing any proposed or final regulations under this subsection, the Administrator shall provide the Secretary of Agriculture an opportunity to comment. Any comments received shall be published with the proposal for final regulation along with the Administrator's response...
- (c) OTHER AUTHORITY. — The Administrator, after notice and opportunity for hearing, is authorized ...
- (3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act, Public Law 91-601) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;
- (4) to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) [packaging and labeling] or section 7 [registration of establishments] of this Act upon his determination that application of such provision is necessary to effectuate the purposes of this Act;
- XV (5) to prescribe regulations requiring any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and
- II (6) to determine and establish suitable names to be used in the ingredient statement.

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As Amended by

PUBLIC LAW 95-95 -- August 7, 1977

"THE CLEAN AIR ACT"

TITLE I -- AIR POLLUTION PREVENTION AND CONTROL

PART A -- AIR QUALITY AND EMISSION LIMITATIONS

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RESEARCH, INVESTIGATION, TRAINING, AND
OTHER ACTIVITIES

IV SEC. 103.

(a) The Administrator shall establish a national research and development program for the prevention and control of air pollution and as part of such program shall --

(1) conduct and promote the coordination and acceleration of research, investigations, experiments, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, and control of air pollution; ...

(3) conduct investigations and research and make surveys concerning any specific problem of air pollution in cooperation with any air pollution control agency with a view to recommending a solution of such problem, if he is requested to do so by such agency or if, in his judgment, such problem may affect any community or communities in a State other than that in which the source of the pollution is located; ...

(b) In carrying out the provisions of the preceding subsection the Administrator is authorized to --

(1) collect and make available, through publications and other appropriate means, the results of and other information pertaining to such research and other activities (including appropriate recommendations by him);

(2) cooperate with other Federal departments and agencies, with air pollution control agencies, with other public and private agencies, institutions, and organizations, and with any industries involved, in the preparation and conduct of such research and other activities;

(3) make grants to air pollution control agencies, to other public or nonprofit private agencies, institutions, and organizations, and to individuals, for purposes stated in subsection (a)(1) above;

(4) contract with public or private agencies, institutions, or organizations, and with individuals; ...

(6) collect and disseminate, in cooperation with other Federal departments and agencies, and with other public or private agencies, institutions, and organizations having related responsibilities, basic data on chemical, physical, and biological effects of varying air quality and other information pertaining to air pollution and the prevention and control thereof...

(c) In carrying out the provisions of subsection (a) of this section the Administration [sic] shall conduct research on, and survey the results of other scientific studies on, the harmful effects on the health or welfare of persons by the various known air pollutants.

(d) The Administrator is authorized to construct such facilities and staff and equip them as he determines to be necessary to carry out his functions under this Act.

IV

(e) If, in the judgment of the Administrator, an air pollution problem of substantial significance may result from discharge or discharges into the atmosphere, he may call a conference concerning this potential air pollution problem to be held in or near one or more of the places where such discharges are occurring. All interested persons shall be given an opportunity to be heard at such conference, either orally or in writing, and shall be permitted to appear in person or by representative. If the Administrator finds, on the basis of evidence presented at such conference, that the discharge or discharges, if permitted, are likely to cause or contribute to air pollution subject to abatement under section 115, he shall send such findings, together with recommendations concerning the measures which he finds reasonable and suitable to prevent such pollution, to the person or persons whose actions will result in the discharge or discharges involved; to air pollution agencies of the State or States and of the municipality or municipalities where such discharge or discharges will originate; and to the interstate air pollution control agency, if any, in the jurisdictional area of which any such municipality is located. Such findings and recommendations shall be advisory only...

(f) (1) In carrying out research pursuant to this Act, the Administrator shall give special emphasis to research on the short- and long-term effects of air pollutants on public health and welfare. In the furtherance of such research, he shall conduct an accelerated research program --

(A) to improve knowledge of the contribution of air pollutants to the occurrence of adverse effects on health, including, but not limited to, behavioral physiological, toxicological, and biochemical effects; and

(B) to improve knowledge of the short- and long-term effects of air pollutants on welfare.

(2) In carrying out the provisions of this subsection the Administrator may --

(A) conduct epidemiological studies of the effects of air pollutants on mortality and morbidity;

(B) conduct clinical and laboratory studies on the immunological, biochemical, physiological, and the toxicological effects including carcinogenic, teratogenic, and mutagenic effects of air pollutants;

(C) utilize, on a reimbursable basis, the facilities of existing Federal scientific laboratories and research centers;

(D) utilize the authority contained in paragraphs (1) through (4) of subsection (b) above; and

(E) consult with other appropriate Federal agencies to assure that research of studies conducted pursuant to this subsection will be coordinated with research and studies of such other Federal agencies.

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AIR QUALITY CRITERIA AND CONTROL TECHNIQUES

II SEC. 108...

(a) (1) ... the Administrator shall publish, and keep current, a list including each air pollutant --

(A) which, causes or contributes to air pollution endangering public health or welfare;

(B) which results from numerous or diverse mobile or stationary sources; and

(C) ... for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria shall reflect the latest scientific knowledge indicating the kind and extent of effects on public health or welfare expected from the presence of such pollutant. The criteria shall include information on --

(A) variable factors (including atmospheric conditions) which may alter the effects of such air pollutant;

(B) the types of air pollutants which may interact with such pollutant to produce an adverse effect; and

(C) any known or anticipated adverse effects.

(b) (1) With the issuance of criteria the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and appropriate air pollution control agencies information on air pollution control techniques, which information shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology. Such information shall include available data on available technology and alternative methods of prevention and control of air pollution, and also include data on alternative fuels, processes, and operating methods which will result in elimination or significant reduction of emissions.

(2) To assist in the development of information on pollution control techniques, the Administrator may establish a standing consulting committee for each air pollutant listed, comprised of technically qualified individuals representative of State and local governments, industry, and the economic community.

(c) The Administrator shall from time to time review, and, as appropriate, modify, and reissue any criteria or information on control techniques issued pursuant to this section...

(f) (1) The Administrator shall publish and make available to appropriate Federal agencies, States, and air pollution control agencies,...

(C) information on measures which may be employed to reduce the impact of air pollution on public health or protect the health of sensitive or susceptible individuals or groups; and

(D) information on the extent to which any process, procedure, or method to reduce or control such air pollutant may cause an increase in the emissions or formation of any other pollutant.

(2) In publishing such information the Administrator shall also include an assessment of --

(A) the relative effectiveness of such processes, procedures, and methods; ...

(C) the environmental, energy, and economic impact of such processes, procedures, and methods.

NATIONAL AMBIENT AIR QUALITY STANDARDS

IV SEC. 109...

(d) (2) (A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee shall complete a review of the [air quality] criteria published under section 108 and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

IMPLEMENTATION PLANS

XVII SEC. 110.

(a) (1) Each State shall, after reasonable notice and public hearings, adopt and submit to the Administrator, within nine months after the promulgation of a national primary ambient air quality standard for any air pollutant, a plan which provides for implementation maintenance, and enforcement of such primary standard in each air quality control region within such State.

(2) The Administrator shall, within four months after the date required for submission of a plan under paragraph (1), approve or disapprove such plan or each portion thereof. The Administrator shall approve such plan, or any portion thereof, if he determines that it was adopted after reasonable notice and hearing and that -- ...

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(C) it includes provisions for establishment and operation of appropriate devices, methods, systems, and procedures necessary to (i) monitor, compile, and analyze data on ambient air quality and, (ii) upon request, make such data available to the Administrator;

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(D) it includes a program to provide for the enforcement of emission limitations and regulation of the modification, construction, and operation of any stationary source, including a permit program as required in parts C and D of this act, and a permit or equivalent program for any major emitting facility, within such region as necessary to assure (i) that national ambient air quality standards are achieved and maintained; and (ii) that a procedure for review of the location of new sources to which a standard of performance will apply prior to construction or modification;...

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(F) ... (ii) it provides requirements for installation of equipment by owners or operators of stationary sources to monitor emissions from such sources, (iii) for periodic reports on the nature and amounts of such emissions; (iv) that such reports shall be correlated by the State agency with any emission limitations or standards established pursuant to this Act, which reports shall be available at reasonable times for public inspection; ...

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(4) The procedure referred to in paragraph (2)(D) for review, prior to construction or modification, of the location of new sources shall (A) provide for adequate authority to prevent the construction or modification of any new source to which a standard of performance under section 111 will apply at any location which the State determines will prevent the attainment or maintenance within any air quality control region within such State of a national ambient air quality primary or secondary standard, and (B) require that prior to commencing construction or modification of any such source, the owner or operator shall submit to such State such information as may be necessary to permit the State to make a determination under clause (A) in this subparagraph...

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(j) As a condition for issuance of any permit, the owner or operator of each new or modified stationary source must show to the satisfaction of the permitting authority that the proposed technological system of continuous emission reduction will enable such source to comply with standards of performance which are to apply and that the construction or modification and operation of such source will be in compliance with all other requirements of this Act.

STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

II SEC. 111...

(b) (1) (A) The Administrator shall publish (and from time to time thereafter shall revise) a list of categories of stationary sources. He shall include a category of sources in such list if in his judgment it causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare...

(f) (2) In determining priorities for promulgating standards of performance for categories of major stationary sources the Administrator shall consider --

(A) the quantity of air pollutant emissions which each such category will emit, or will be designed to emit;

(B) the extent to which each such pollutant may reasonably be anticipated to endanger public health or welfare; and

(C) the mobility and competitive nature of each such category of sources and the consequent need for nationally applicable new source standards of performance...

(g) (5) Upon application by the Governor of a State showing that the Administrator has failed to list any air pollutant which causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness as a hazardous air pollutant under section 112, the Administrator shall revise the list of hazardous air pollutants under such section to include such pollutant...

(7) Unless later deadlines for action of the Administrator are otherwise prescribed under this section or section 112, the Administrator shall, not later than three months following the date of receipt of any application by a Governor of a State, either --

(A) find that such application does not contain the requisite showing and deny such application, or

(B) grant such application and take the action required under this subsection...

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- (j) (1) (A) Any person proposing to own or operate a new source may request the Administrator for waivers from the requirements of this section for such source with respect to any air pollutant to encourage the use of an innovative technological system or systems of continuous emission reduction. The Administrator may grant a waiver if he determines that -- ...

(iii) the owner or operator of the proposed source has demonstrated to the satisfaction of the Administrator that the proposed system will not cause or contribute to any unreasonable risk to public health, welfare, or safety in its operation, function, or malfunction, and...

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... The Administrator may conduct such tests and may require the owner or operator of the proposed source to conduct such tests and provide such information as is necessary to carry out clause (iii) above, of this subparagraph. Such requirements shall include a requirement for prompt reporting of the emission of any unregulated pollutant from a system if such pollutant was not emitted, or was emitted in significantly lesser amounts without the use of such system...

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NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

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SEC. 112.

- (a) For purposes of this section --

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(1) "Hazardous air pollutant" means an air pollutant for which no ambient air quality standard is applicable and which in the judgment of the Administrator causes, or contributes to, air pollution which may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness...

- (b) (1) (A) The Administrator shall publish (and shall from time to time thereafter revise) a list which includes each hazardous air pollutant for which he intends to establish an emission standard under this section.

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(B) Within 180 days after the inclusion of any air pollutant in the list, the Administrator shall publish proposed regulations establishing emission standards for such pollutant together with a notice of public hearing within

thirty days. Not later than 180 days after such publication, the Administrator shall prescribe an emission standard, unless he finds, on the basis of information presented at such hearings, that such pollutant clearly is not a hazardous air pollutant. The Administrator shall establish any standard at the level which provides an ample margin of safety to protect the public health.

(C) Any emission standard established pursuant to this section shall become effective upon promulgation.

(2) The Administrator shall, from time to time, issue information on pollution control techniques for air pollutants subject to the provisions of this section.

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(c) (1) After the effective date of any emission standard under this section --

(A) no person may construct any new source or modify any existing source which will emit an air pollutant to which a standard applies unless the Administrator finds that such source if properly operated will not cause emissions in violation of such standard, and

(B) no air pollutant to which such standard applies may be emitted from any stationary source in violation of such standard, except that in the case of an existing source --

(i) such standard shall not apply until 90 days after its effective date, and

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(ii) the Administrator may grant a waiver permitting such source up to two years to comply with the standard, if he finds that such period is necessary for the installation of controls and that steps will be taken during the period of the waiver to assure that the health of persons will be protected from imminent danger...

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INSPECTIONS, MONITORING, AND ENTRY

SEC. 114.

(a) For the purpose (i) of developing or assisting in the development of any implementation plan, any standard of performance, or any emission standard, (ii) of determining whether any person is in violation of any such standard or any requirement of a plan, or (iii) of carrying out any provision of this Act --

VII (1) the Administrator may require any person who owns or
V operates any emission source or who is subject to any requirement
XII of this Act to (A) establish and maintain such records, (B) make
such reports, (C) install, use, and maintain such monitoring
equipment or methods, (D) sample such emissions (in accordance with
such methods, at such locations, at such intervals, and in such
manner as the Administrator shall prescribe), and (E) provide such
other information, as he may reasonably require; and

VIII (2) the Administrator or his authorized representative, upon
presentation of his credentials --

(A) shall have a right of entry to, upon, or through any
premises of such person or in which any records required to be
maintained under paragraph (1) of this section are located,
and

(B) may at reasonable times have access to and copy any
records, inspect any monitoring equipment and method required
under paragraph (1), and sample any emissions which such
person is required to sample under paragraph (1)...

XIV (c) Any records, reports, or information obtained under subsection
(a) shall be available to the public, except that upon a showing
satisfactory to the Administrator by any person that records, reports,
or information, or particular part thereof, (other than emission data)
to which the Administrator has access under this section if made public
would divulge methods or processes entitled to protection as trade
secrets, the Administrator shall consider such information confidential
in accordance with the purposes of section 1905 of title 18 of the
United States Code, except that such information may be disclosed to
other officers, employees, or authorized representatives of the United
States concerned with carrying out this Act or when relevant in any
proceeding under this Act.

* * *

PRESIDENT'S AIR QUALITY ADVISORY BOARD AND ADVISORY COMMITTEES

IV SEC. 117.

(a) In order to obtain assistance in the development and imple-
mentation of the purposes of this Act including air quality criteria,
recommended control techniques standards, research and development, and
to encourage the continued efforts on the part of industry to improve

air quality and to develop economically feasible methods for the control and abatement of air pollution, the Administrator shall from time to time establish advisory committees. Committee members shall include, but not be limited to, persons who are knowledgeable concerning air quality from the standpoint of health, welfare, economics, or technology...

(c) Prior to --

(1) issuing criteria for an air pollutant under paragraph 108(a)(2),

(2) publishing any list under subparagraph 111(b)(1)(A) or 112(b)(1)(A),

(3) publishing any standard under subparagraph 111(b)(1)(B) or subparagraph 112(b)(1)(B)...

the Administrator shall, to the maximum extent practicable within the time provided, consult with appropriate advisory committees, independent experts, and Federal departments and agencies.

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PART B -- OZONE PROTECTION

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STUDIES BY ENVIRONMENTAL PROTECTION AGENCY

III SEC. 153.

(a) The Administrator shall conduct a study of the cumulative effect of all substances, practices, processes, and activities which may affect the stratosphere, especially ozone in the stratosphere. The study shall include an analysis of the independent effects on the stratosphere, especially such ozone in the stratosphere of --

- (1) the release into the ambient air of halocarbons,
- (2) the release into the ambient air of other sources of chlorine,
- (3) the uses of bromine compounds, and
- (4) emissions of aircraft and aircraft propulsion systems employed by operational and experimental aircraft.

The study shall also include such physical, chemical, atmospheric, biomedical, or other research and monitoring as may be necessary to ascertain (A) any direct or indirect effects upon the public health and welfare of changes in the stratosphere, especially ozone in the stratosphere, and (B) the probable causes of changes in the stratosphere, especially the ozone in the stratosphere.

(b) The Administrator shall undertake research on --

(1) methods to recover and recycle substances which directly or indirectly affect the stratosphere, especially ozone in the stratosphere,

(2) methods of preventing the escape of such substances,

(3) safe substitutes for such substances, and

(4) other methods to regulate substances, practices, processes, and activities which may reasonably be anticipated to affect the stratosphere, especially ozone in the stratosphere...

RESEARCH AND MONITORING BY OTHER AGENCIES

II SEC. 154.

(a) The Administrator of the National Oceanic and Atmospheric Administration shall establish a continuing program of research and monitoring of the stratosphere for the purpose of early detection of changes in the stratosphere and climatic effects of such changes. Such Administrator shall on or before January 1, 1978, and biennially thereafter, transmit a report to the Administrator and the Congress on the findings of such research and monitoring. Such report shall contain any appropriate recommendations for legislation or regulation.

(b) The National Aeronautics and Space Administration shall continue programs of research, technology, and monitoring of the stratosphere for the purpose of understanding the physics and chemistry of it and for the early detection of potentially harmful changes in the ozone in it. Such Administration shall transmit reports by January 1, 1978, and biennially thereafter, to the Administrator and the Congress on the results of the programs authorized in this subsection, together with any appropriate recommendations for legislation or regulation.

(c) The Director of the National Science Foundation shall encourage and support ongoing stratospheric research programs and continuing research programs that will increase scientific knowledge of the effects of changes in the ozone layer in the stratosphere upon living organisms and ecosystems. Such Director shall transmit reports by

January 1, 1978, and biennially thereafter, to the Administrator and the Congress on the results of such programs, together with any appropriate recommendations for legislation or regulation.

(d) The Secretary of Agriculture shall encourage and support continuing research programs that will increase scientific knowledge of the effects of changes in the ozone in the stratosphere upon animals, crops, and other plant life. Such Secretary shall transmit reports by January 1, 1978, and biennially thereafter, to the Administrator and the Congress on the results of such programs, together with any appropriate recommendations for legislation or regulation.

(e) The Secretary of Health, Education, and Welfare shall encourage and support continuing research programs that will increase scientific knowledge of the effects of changes in the ozone in the stratosphere upon human health. Such Secretary shall transmit reports by January 1, 1978, and biennially thereafter, to the Administrator and the Congress on the results of such programs, together with any appropriate recommendations for legislation or regulation.

(f) In carrying out subsection (a) through (e) of this section, the agencies involved (1) shall enlist and encourage cooperation and assistance from other Federal agencies, universities, and private industry, and (2) shall solicit the views of the Administrator with regard to plans for the research involved so that any such research will, if regulatory action by the Administrator is indicated, provide the preliminary information base for such action.

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PART C -- PREVENTION OF SIGNIFICANT DETERIORATION OF AIR QUALITY

SUBPART 1

* * *

PRECONSTRUCTION REQUIREMENTS

X SEC. 165.

(a) No major emitting facility on which construction is commenced after the date of the enactment of this part, may be constructed in any area to which this part applies unless --

(1) a permit has been issued setting forth emission limitations for such facility;

(2) the proposed permit has been subject to a review in accordance with this section, the required analysis has been conducted in accordance with regulations promulgated by the Administrator, and a public hearing has been held with opportunity for interested persons including representatives of the Administrator to appear and submit written or oral presentations on the air quality impact of such source, alternatives thereto, control technology requirements, and other appropriate considerations;

(3) the owner or operator of such facility demonstrates, that emissions from construction or operation of such facility will not cause, or contribute to, air pollution in excess of any (A) maximum allowable increase or maximum allowable concentration for any pollutant in any area to which this part applies more than one time per year, (B) national ambient air quality standard in any air quality control region, or (C) any other applicable emission standard of performance under this Act;

(4) the proposed facility is subject to the best available control technology for each pollutant subject to regulation under this Act emitted from, or which results from, such facility;

(5) the provisions of subsection (d) with respect to protection of class I areas have been complied with for such facility;

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(6) there has been an analysis of any air quality impacts projected for the area as a result of growth associated with such facility;

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(7) the owner or operator agrees to conduct such monitoring as may be necessary to determine the effect which emissions from any such facility may have on air quality in any areas which may be affected by emissions for such source; and

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(8) ... the Administrator has approved the determination of best available technology as set forth in the permit...

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(e) (1) The review provided for in subsection (a) above shall be preceded by an analysis, in accordance with regulations of the Administrator, conducted by any general purpose unit of local government or by the applicant, of the ambient air quality at the proposed site and in areas which may be affected by emissions from such facility for each pollutant subject to regulation under this Act which will be emitted from such facility...

(3) The Administrator shall promulgate regulations respecting the analysis which -- ...

(B) shall require analysis of the ambient air quality, climate and meteorology, terrain, soils, and vegetation, and visibility at the site of the proposed major emitting facility and in the area potentially affected by the emissions from such facility for each pollutant regulated under this Act, which will be emitted from, or which results from the construction or operation of, such facility, the size and nature of the proposed facility, and such other factors as may be relevant in determining the effect of emissions from a proposed facility on any air quality control region...

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PART D -- PLAN REQUIREMENTS FOR NONATTAINMENT AREAS

DEFINITIONS

SEC. 171.

For the purpose of this part and subparagraph 110(a)(2)(I) above --

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(1) "Reasonable further progress" means annual incremental reductions in emissions of the applicable air pollutant (including substantial reductions in the early years following approval or promulgation of plan provisions under this part and subparagraph 110(a)(2)(I) above, and regular reductions thereafter) which are sufficient, in the judgment of the Administrator to provide for attainment of the applicable national ambient air quality standard...

NONATTAINMENT PLAN PROVISIONS

SEC. 172...

(b) The plan provisions required by subsection (a) above shall --
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(1) be adopted by the State after reasonable notice and public hearing;...

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(4) include a comprehensive, accurate, current inventory of actual emissions from all sources of each such pollutant for each such area...;

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(5) expressly identify and quantify the emissions, if any, of any such pollutant which will be allowed to result from the construction and operation of major new or modified stationary sources for each such area;

- X (6) require permits for the construction and operation of new or modified major stationary sources in accordance with section 173 (relating to permit requirements);...

PERMIT REQUIREMENTS

X SEC. 173.

The permit program required by paragraph 172(b)(6) above shall provide that permits to construct and operate may be issued if --

(1) the permitting agency determines that --

(A) by the time the source is to commence operation, total allowable emissions from existing sources in the region, from new or modified sources which are not major emitting facilities, and from the proposed source will be sufficiently less than total emissions from existing sources prior to the application as to represent (when required under section 172) reasonable further progress; or

(B) that emissions resulting from the proposed new or modified major stationary source will not cause or contribute to emission levels which exceed the allowance permitted for such pollutant for such area from new or modified major stationary sources under subsection 172(b) above;

(2) the proposed source is required to comply with the lowest achievable emission rate;

(3) the owner or operator of the proposed new or modified source has demonstrated that all major stationary sources owned or operated by such persons in such State are subject to emission limitations and are in compliance, or on a schedule for compliance, with all applicable emission limitations and standards under this Act; and ...

Any emission reductions required as a precondition of the issuance of a permit under subparagraph (1)(A) above shall be legally binding before such permit may be issued.

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REGULATION OF FUELS

X SEC. 211.

(a) The Administrator may by regulation designate any fuel or fuel additive and, after such date or dates as may be prescribed by him, no

manufacturer or processor of any such fuel or additive may sell, offer for sale, or introduce into commerce such fuel or additive unless the Administrator has registered such fuel or additive in accordance with subsection (b) of this section.

(b) (1) For the purpose of registration of fuels and fuel additives, the Administrator shall require --

(A) the manufacturer of any fuel to notify him as to the commercial identifying name and manufacturer of any additive contained in such fuel; the range of concentration of any additive in the fuel; and the purpose-in-use of any such additive; and

(B) the manufacturer of any additive to notify him as to the chemical composition of such additive.

(2) For the purpose of registration of fuels and fuel additives, the Administrator may also require the manufacturer of any fuel or fuel additive --

I (A) to conduct tests to determine potential public health effects of such fuel or additive (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects), and

XII (B) to furnish a description of any analytical technique that can be used to detect and measure any additive in such fuel, the recommended range of concentration of such additive, and the recommended purpose-in-use of such additive, and such other information as is reasonable and necessary to determine the emissions resulting from the use of the fuel or additive contained in such fuel, the effect of such fuel or additive on the emission control performance of any vehicle or vehicle engine, or the extent to which such emissions affect the public health or welfare.

II Tests under subparagraph (A) shall be conducted in conformity with test procedures and protocols established by the Administrator. The results of such tests shall not be considered confidential.

XIV (3) Upon compliance with the provisions of this subsection, including assurance that the Administrator will receive changes in the information required, the Administrator shall register such fuel or fuel additive.

(c) (1) The Administrator may, from time to time on the basis of information obtained under subsection (b) of this section or other information available to him, by regulation, control or prohibit the manufacture, introduction into commerce, offering for

sale, or sale of any fuel or fuel additive for use in a motor vehicle or motor vehicle engine (A) if in the judgment of the Administrator any emission product of such fuel or fuel additive causes, or contributes, to air pollution which may reasonably be anticipated to endanger the public health or welfare, or (B) if emission products of such fuel or fuel additive will impair to a significant degree the performance of any emission control device or system which is in general use, or which the Administrator finds has been developed to a point where in a reasonable time it would be in general use were such regulation to be promulgated.

(2) (A) No fuel, classes of fuels, or fuel additive may be controlled or prohibited by the Administrator pursuant to clause (A) of paragraph (1) except after consideration of all relevant medical and scientific evidence available to him, including consideration of other technologically or economically feasible means of achieving emission standards under section 202.

(B) No fuel or fuel additive may be controlled or prohibited by the Administrator pursuant to clause (B) of paragraph (1) except after consideration of available scientific and economic data, including a cost-benefit analysis comparing emission control devices or systems which are or will be in general use and require the proposed control or prohibition with emission control devices or systems which are or will be in general use and do not require the proposed control or prohibition. On request of a manufacturer of motor vehicle engines, fuels, or fuel additives submitted within 10 days of notice of proposed rulemaking, the Administrator shall hold a public hearing and publish findings with respect to any matter he is required to consider under this subparagraph. Such findings shall be published at the time of promulgation of final regulations.

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(C) No fuel or fuel additive may be prohibited by the Administrator under paragraph (1) unless he finds, and publishes such finding, that in his judgment such prohibition will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited.

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TITLE III -- GENERAL

ADMINISTRATION

VII SEC. 301.

(a) (1) The Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this Act. The Administrator may delegate to any officer or employee of the Environmental Protection Agency such of his powers and duties under this Act, except the making of regulations, as he may deem necessary or expedient.

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GENERAL PROVISIONS RELATING TO ADMINISTRATIVE
PROCEEDINGS AND JUDICIAL REVIEW

SEC. 307.

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(a) (1) In connection with any determination under section 110(f) [regional energy emergency] or section 202(b)(5) [automobile emission standard waivers], or for purposes of obtaining information under section 202(b)(4) [report to Congress -- automobile emissions] or 211(c)(3) [regulation of fuels], the Administrator may issue subpoenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and he may administer oaths. Except for emission data, upon a showing satisfactory to the Administrator by such owner or operator that such papers, books, documents, or information or particular part thereof, if made public, would divulge trade secrets or secret processes, the Administrator shall consider such record, report, or information or particular portion thereof confidential in accordance with the purposes of section 1905 of title 18 of the United States Code, except that such paper, book, document, or information may be [disclosed] to other officers, employees, or authorized representatives of the United States concerned with carrying out this Act, to persons carrying out the National Academy of Sciences study and investigation provided for in section 202(c), or when relevant in any proceeding under this Act...

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(d) (3) In the case of any rule under this Act, notice of proposed rulemaking shall be published in the Federal Register, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment. The statement of basis and purpose shall include a summary of --

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data; and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 109(d) and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

* * *

POLICY REVIEW

II SEC. 309.

(a) The Administrator shall review and comment in writing on the environmental impact of any: (1) legislation proposed by any Federal department or agency, (2) newly authorized Federal projects for construction and any major Federal agency action, and (3) proposed regulations published by any department or agency of the Federal Government. Such written comment shall be made public at the conclusion of any such review.

(b) In the event the Administrator determines that any such legislation, action, or regulation is unsatisfactory from the standpoint of public health or welfare or environmental quality, he shall publish his determination and the matter shall be referred to the Council on Environmental Quality.

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AIR QUALITY MONITORING

II V SEC. 319.

Not later than August 7, 1978, the Administrator shall promulgate regulations establishing an air quality monitoring system throughout the United States which —

(1) utilizes uniform air quality monitoring criteria and methodology and measures such air quality according to a uniform air quality index,

(2) provides for air quality monitoring stations in major urban areas and other appropriate areas throughout the United States to provide monitoring such as will supplement (but not duplicate) air quality monitoring carried out by the States required under any applicable implementation plan,

(3) provides for daily analysis and reporting of air quality based upon such uniform air quality index, and

(4) provides for record-keeping with respect to such monitoring data and for periodic analysis and reporting to the general public by the Administrator with respect to air quality based upon such data...

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NATIONAL COMMISSION ON AIR QUALITY

IV SEC. 323.

(a) There is established a National Commission on Air Quality which shall study and report to the Congress on --

(1) available alternatives, including enforcement mechanisms to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and to achieve the other purposes of the Act, including achievement and maintenance of national ambient air quality standards and, in accordance with paragraph (b)(2) below, the prevention of significant deterioration of air quality;

(2) the economic, technology, and environmental consequences of achieving or not achieving the purposes of this Act and programs authorized by it;...

(4) air pollutants not presently regulated, which pose or may in the future pose a threat to public health or public welfare and options available to regulate emissions of such pollutants;

(5) the adequacy of research, development, and demonstrations being carried out by Federal, State, local, and nongovernmental entities to protect and enhance air quality; ...

(8) (A) the special problems of small businesses and government agencies in obtaining reductions of emissions from existing sources in order to offset increases in emissions from new sources for the purposes of this Act; and

(B) alternative strategies for permitting (without impeding the achievement of national ambient air quality standards as expeditiously as possible) the construction and modification of facilities in air quality control regions currently exceeding the national ambient air quality standard for any pollutant regulated under the Act.

(b) (1) Studies and investigations conducted pursuant to subsection (a) shall include the effects of existing or proposed national ambient air quality standards on employment, energy, and the economy (including State and local), their relationship to objective scientific and medical data collected to determine their validity, as well as other social and environmental effects of national ambient air quality standards...

III

(e) The heads of the departments, agencies, and instrumentalities of the executive branch of the Federal Government shall cooperate with the Commission in carrying out the requirements of this section, and shall furnish to the Commission such information as the Commission deems necessary to carry out this section...

(g) Reports shall be submitted with regard to all Commission studies and investigations, together with any appropriate recommendations, not later than August 17, 1980. Upon submission of such report or upon expiration of such three-year period, whichever is sooner, the Commission shall cease to exist.

* * *

PROVISIONS OF PUBLIC LAW 95-95 WHICH DO NOT AMEND
AND THEREFORE ARE NOT PARTS OF THE CLEAN AIR ACT

(The section numbers below refer to the sections of 95-95 and not the Clean Air Act.)

UNREGULATED POLLUTANTS

II

SEC. 120...

(b) The Administrator of the Environmental Protection Agency shall conduct a study, in conjunction with other appropriate agencies, concerning the effect on the public health and welfare of sulfates,

radioactive pollutants, cadmium, arsenic, and polycyclic organic matter which are present or may reasonably be anticipated to occur in the ambient air. Such study shall include a thorough investigation of how sulfates are formed and how to protect public health and welfare from the injurious effects, if any, of sulfates, cadmium, arsenic, and polycyclic organic matter.

* * *

INTERAGENCY COOPERATION ON PREVENTION OF ENVIRONMENTAL
CANCER AND HEART AND LUNG DISEASE

III SEC. 402.

(a) Not later than November 7, 1977, there shall be established a Task Force on Environmental Cancer and Heart and Lung Disease (hereinafter referred to as the "Task Force"). The Task Force shall include representatives of the Environmental Protection Agency, the National Cancer Institute, the National Institute of Occupational Safety and Health, and the National Institute on Environmental Health Sciences, and shall be chaired by the Administrator (or his delegate).

(b) The Task Force shall --

(1) recommend a comprehensive research program to determine and quantify the relationship between environmental pollution and human cancer and heart and lung disease;

(2) recommend comprehensive strategies to reduce or eliminate the risks of cancer or such other diseases associated with environmental pollution;

(3) recommend research and such other measures as may be appropriate to prevent or reduce the incidence of environmentally-related cancer and heart and lung diseases;

(4) coordinate research by, and stimulate cooperation between, the Environmental Protection Agency, the Department of Health, Education and Welfare, and such other agencies as may be appropriate to prevent environmentally-related cancer and heart and lung diseases; and

(5) report to Congress, not later than August 7, 1978, and annually thereafter, on the problems and progress in carrying out this section.

STUDIES

II SEC. 403.

(a) Not later than January 7, 1979, the Administrator of the Environmental Protection Agency, in cooperation with the National Academy of Sciences, shall study and report to Congress on (1) the relationship between the size, weight, and chemical composition of suspended particulate matter (especially with respect to fine particulate matter) and (2) the availability of technology for controlling such particulate matter.

(b) The Administrator of the Environmental Protection Agency shall conduct a study and report to the Congress not later than January 1, 1979, on the effects on public health and welfare of odors or odorous emissions, the sources of such emissions, the technology or other measures available for control of such emissions and the costs of such technology or measures, and the costs and benefits of alternative measures or strategies to abate such emissions. Such reports shall include an evaluation of whether air quality criteria or national ambient air quality standards should be published under the Clean Air Act for odors, and what other strategies or authorities under the Clean Air Act are available or appropriate for abating such emissions.

(c) (1) Not later than August 7, 1978, the Administrator of the Environmental Protection Agency shall publish throughout the United States a list of all known chemical contaminants resulting from environmental pollution which have been found in human tissue including blood, urine, breast milk, and all other human tissue. Such list shall be prepared for the United States and shall indicate the approximate number of cases, the range of levels found, and the mean levels found.

(2) Not later than January 7, 1979, the Administrator shall publish in the same manner an explanation of what is known about the manner in which the chemicals described in paragraph (1) entered the environment and thereafter human tissue.

(3) The Administrator, in consultation with National Institutes of Health, the National Center for Health Statistics, and the National Center for Health Services Research and Development, shall, if feasible, conduct an epidemiological study to demonstrate the relationship between levels of chemicals in the environment and in human tissue. Such study shall be made in appropriate regions or areas of the United States in order to determine any different results in such regions or areas. The results of such study shall, as soon as practicable, be reported to the appropriate committee of the Congress.

(d) The Administrator of the Environmental Protection Agency shall conduct a study of air quality in various areas throughout the country, including the Gulf Coast region. Such study shall include analysis of liquid and solid aerosols and other fine particulate matter and the contribution of such substances to visibility and public health problems in such areas. For the purposes of this study, the Administrator shall use environmental health experts from the National Institutes of Health and other outside agencies and organizations.

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[33 U.S.C. 466 et. seq. -- Last Amended December 1977]

"THE CLEAN WATER ACT"

In the Federal Water Pollution Control Act Congress assigned numerous specific information development and research responsibilities to the Administrator. In accordance with our classification scheme, much of the Act should be assigned to categories II and III. Because the results of the required studies represent a significant source of information on current pollution patterns and pollution control technology, we have included these sections.

[33 U.S.C. et seq. -- Amended December 1977]

"THE CLEAN WATER ACT"

TITLE I -- RESEARCH AND RELATED PROGRAMS

DECLARATION OF GOALS AND POLICY

XVII SEC. 101.

(a) (6) It is the national policy that a major research and demonstration effort be made to develop technology necessary to eliminate the discharge of pollutants into the navigable waters, waters of the contiguous zone, and the oceans.

(b) It is further the policy of the Congress to support and aid research relating to the prevention, reduction, and elimination of pollution, and to provide Federal technical services and financial aid to State and interstate agencies and municipalities in connection with the prevention, reduction, and elimination of pollution...

(f) It is the national policy that to the maximum extent possible the procedures utilized for implementing this Act shall encourage the drastic minimization of paperwork and interagency decision procedures, and the best use of available manpower and funds, so as to prevent needless duplication and unnecessary delays at all levels of government...

COMPREHENSIVE PROGRAMS FOR WATER POLLUTION CONTROL

SEC. 102.

III

(a) For the purpose of establishing comprehensive programs for water pollution control, the Administrator is authorized to make joint investigations with any Federal, State, interstate and local agencies of the condition of any waters in any State or States, and of the discharges of any sewage, industrial wastes, or substance which may adversely affect such waters.

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RESEARCH, INVESTIGATIONS, TRAINING AND INFORMATION

II
III

SEC. 104.

(a) The Administrator shall establish national programs for the prevention, reduction, and elimination of pollution and as part of such programs shall --

(1) in cooperation with other Federal, State, and local agencies, conduct and promote the coordination and acceleration of research, investigations, experiments, training, demonstrations, surveys, and studies relating to the causes, effects, extent, prevention, reduction and elimination of pollution;

(2) encourage, cooperate with, and render technical services to pollution control agencies and other appropriate public or private agencies, institutions, and other organizations, and individuals, including the general public, in the conduct of activities referred to in paragraph (1) above;

IV

(3) conduct ... public investigations concerning the pollution of any navigable waters, and report the results;

IV

(4) establish advisory committees composed of recognized experts in various aspects of pollution and representatives of the public to assist in the examination and evaluation of research progress and proposals and to avoid duplication of research;

V

(5) ... establish, equip, and maintain a water quality surveillance system for the purpose of monitoring the quality of the navigable waters, ground waters, the contiguous zone and the oceans, and the Administrator shall, to the extent practicable, conduct such surveillance utilizing the resources of the National Aeronautics and Space Administration, the National Oceanic and Atmospheric Administration, the Geological Survey, and the Coast Guard, and shall report on such quality in the report required under subsection 516(a) below; and

(6) initiate and promote the coordination and acceleration of research designed to develop the most effective practicable tools and techniques for measuring the social and economic costs and benefits of activities which are subject to regulation under this Act, and shall transmit a report on the results of such research to the Congress not later than January 1, 1974.

(b) In carrying out the provisions of subsection (a) above, the Administrator is authorized to --

(1) collect and make available through appropriate means, the results of the research and other activities referred to in this section, as well as any other information or recommendations he has in regards to such research and activities;

(2) cooperate with other Federal departments and agencies, State water pollution control agencies, interstate agencies, other public and private agencies, institutions, organizations, industries involved, and individuals, in the preparation and conduct of such research and other activities referred to in this section;

(3) make grants to State water pollution control agencies, interstate agencies, other public or non-profit private agencies, institutions, organizations, and individuals, for purposes stated in paragraph (1) of subsection (a) above;

(4) contract with public or private agencies, institutions, organizations, and individuals, without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C 529; 41 U.S.C. 5);...

(6) collect and disseminate ..., basic data on chemical, physical, and biological effects of varying water quality and other information pertaining to pollution and the prevention, reduction, and elimination thereof; and

(7) develop effective and practical processes, methods, and prototype devices for the prevention, reduction, and elimination of pollution.

(c) In carrying out the provisions of subsection 104(a) above, the Administrator shall conduct research on, and survey the results of other scientific studies on, the harmful effects on the health or welfare of persons caused by pollutants. In order to avoid duplication of effort, the Administrator shall, to the extent practicable, conduct such research in cooperation with and through the facilities of the Secretary of Health, Education, and Welfare.

(d) In carrying out the provisions of this section the Administrator shall develop and demonstrate under varied conditions (including conducting such basic and applied research, studies, and experiments as may be necessary);...

(2) Improved methods and procedures to identify and measure the effects of pollutants, including those pollutants created by new technological developments; and...

(e) The Administrator shall establish, equip, and maintain at least six laboratory and research facilities..., for the conduct of research, investigations, experiments, field demonstrations and studies, and training relating to the prevention, reduction and elimination of pollution. Insofar as practicable, each such facility shall be located near institutions of higher learning in which graduate training in such research might be carried out.

(f) The Administrator shall conduct research and technical development work, and make studies, with respect to the waters of the Great Lakes, including an analysis of ..., an evaluation of municipal, industrial, and vessel waste treatment and disposal practices with respect to such waters, and a study of alternate means of solving pollution problems (including additional waste treatment measures) with respect to such waters...

(h) The Administrator is authorized to enter into contracts with, or make grants to, public or private agencies and organizations and individuals for the purpose of developing and demonstrating new or improved methods for the prevention, removal, reduction, and elimination of pollution in lakes...

(i) The Administrator, in cooperation with the Coast Guard, shall --

(1) engage in such research, studies, experiments, and demonstrations as he deems appropriate, relative to the removal of oil from any waters and to the prevention, control, and elimination of oil and hazardous substances pollution;

(2) publish from time to time the results of such activities; and...

In carrying out this subsection, the Administrator may enter into contracts with, or make grants to, public or private agencies and organizations and individuals...

(1) (1) The Administrator shall, after consultation with appropriate agencies and organizations and not later than January 1, 1973, develop and issue to the States the latest scientific knowledge available indicating the kind and extent of effects on health and welfare which may be expected from the presence of pesticides in the water in varying quantities. He shall revise and add to such information whenever necessary to reflect developing scientific knowledge.

(2) The President shall, in consultation with appropriate agencies and organizations conduct studies and investigations of methods to control the release of pesticides into the environment which studies shall include examination of the persistency of pesticides in the water environment and alternatives thereto. The President shall submit such reports, from time to time to Congress.

(m) (1) The Administrator shall conduct a study of (A) the generation of used engine, machine, cooling, and similar waste oil, including quantities generated, the nature and quality of such oil, present collecting methods and disposal practices, and alternate uses of such oil; (B) the long-term chronic biological effects of the disposal of such waste oil; and (C) the potential market for such oils, including the economic and legal factors relating to the sale of products made from such oils, the level of subsidy, if any, needed to encourage the purchase by public and private non-profit agencies of products from such oil, and the practicability of Federal procurement, on a priority basis, of products made from such oil.

(2) The Administrator shall report the preliminary results of such study to Congress before April 18, 1973, and shall submit a final report to Congress before April 18, 1974.

(n) (1) The Administrator shall, in cooperation with appropriate public bodies, private organizations, institutions, and individuals, conduct, promote, and encourage contributions to, continuing comprehensive studies of the effects of pollution, including sedimentation, in the estuaries and estuarine zones of the United States on fish and wildlife and on other beneficial purposes. Such studies shall also consider the effect of demographic trends, the exploitation of mineral resources and fossil fuels, land and industrial development, navigation, flood and erosion control, and other uses of estuaries and estuarine zones upon the pollution of the waters therein.

(2) In conducting such studies, the Administrator shall assemble, coordinate, and organize all existing pertinent information on the Nation's estuaries and estuarine zones; carry out a program of investigations and surveys to supplement existing information in representative estuaries and estuarine zones; and identify the problems and areas where further research and study are required.

(3) The Administrator shall submit to Congress, from time to time, reports of the studies authorized by this subsection but at least one such report during any six-year period. Copies of each report shall be made available to all interested parties, public and private...

(p) In carrying out the provisions of subsection (a) above, the Administrator shall, in cooperation with the Secretary of Agriculture, other Federal agencies, and the States, carry out a comprehensive study and research program to determine new and improved methods of preventing, reducing, and eliminating pollution from agriculture, including the legal, economic, and other implications of the use of such methods...

(r) The Administrator is authorized to make grants to colleges and universities to conduct basic research into the structure and function of fresh water aquatic ecosystems, and to improve understanding of the ecological characteristics necessary to the maintenance of the chemical, physical, and biological integrity of freshwater aquatic ecosystems.

(s) The Administrator is authorized to make grants to one or more institutions of higher education [regionally located and to be designated as "River Study Centers"] for the purpose of conducting and reporting on interdisciplinary studies on the nature of river systems, including hydrology, biology, ecology, economics, the relationship between river uses and land uses, and the effects of development within river basins on river systems and on the value of water resources and water related activities. No such grant in any fiscal year shall exceed \$1,000,000...

GRANTS FOR RESEARCH AND DEVELOPMENT

II SEC. 105...

III

(c) In order to carry out the purposes of section 301 [effluent limitations], the Administrator is authorized to (1) conduct in the Environmental Protection Agency, (2) make grants to persons, and (3) enter into contracts with persons, for research and demonstration projects for prevention of pollution of any waters by industry including, but not limited to, the prevention, reduction, and elimination of the discharge of pollutants. No grant shall be made for any project under this subsection unless the Administrator determines that such project will develop or demonstrate a new or improved method of treating industrial wastes or otherwise prevent pollution by industry, which method shall have industry-wide application.

(d) In carrying out the provisions of this section, the Administrator shall conduct, on a priority basis, an accelerated effort to develop, refine, and achieve practical application of:

(1) waste management methods applicable to point and non-point sources of pollutants to eliminate the discharge of pollutants, including, but not limited to, elimination of runoff of pollutants and the effects of pollutants from in-place or accumulated sources;

(2) advanced waste treatment methods applicable to point and non-point sources, including in-place or accumulated sources of pollutants, and methods for reclaiming and recycling water and confining pollutants so they will not migrate to cause water or other environmental pollution; and

(3) improved methods and procedures to identify and measure the effects of pollutants on the chemical, physical, and biological integrity of water, including those pollutants created by new technological developments.

(e) (1) The Administrator is authorized to (A) make, in consultation with the Secretary of Agriculture, grants to persons for research and demonstration projects with respect to new and improved methods of preventing, reducing, and eliminating pollution from agriculture, and (B) disseminate, in cooperation with the Secretary of Agriculture, such information obtained under this subsection, section 104(p) above and section 304 [information and guidelines] as will encourage and enable the adoption of such methods in the agricultural industry ...

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IN-PLACE TOXIC POLLUTANTS

II
III SEC. 115.

The Administrator is directed to identify the location of in-place pollutants with emphasis on toxic pollutants in harbors and navigable waterways and is authorized, acting through the Secretary of the Army, to make contracts for the removal and appropriate disposal of such materials from critical port and harbor areas...

TITLE II -- GRANTS FOR CONSTRUCTION OF
TREATMENT WORKS

* * *

AREAWIDE WASTE TREATMENT MANAGEMENT

SEC. 208...

(b) (2) Any areawide waste treatment management plan shall include, but not be limited to ...

XVII (K) a process to control the disposal of pollutants on land or in subsurface excavations within such area to protect ground and surface water quality.

* * *

TITLE III -- STANDARDS AND ENFORCEMENT

EFFLUENT LIMITATIONS

II SEC. 301...

(a) Except in compliance with this section and sections 302, 306, 307, 318, 402 and 404, the discharge of any pollutant shall be unlawful.

(b) [The Administrator shall establish and enforce the following effluent limitations based on availability of technology]...

(c) [modifications of requirements of effluent limitations]

X

(d) Any effluent limitation required by paragraph (b)(2) above, shall be reviewed at least every five years and, if appropriate, revised pursuant to the procedure established under such paragraph...

(g)-(1) [modifications of requirements of effluent limitations]

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WATER QUALITY STANDARDS AND IMPLEMENTATION PLANS

SEC. 303...

IV

(c) (1) The Governor of a State or the State water pollution control agency shall at least once each three years hold public hearings for the purpose of reviewing, modifying and adopting applicable water quality standards. Results of such review shall be made available to the Administrator.

(2) Whenever the State revises or adopts a new standard, it shall be submitted to the Administrator...

(3) If the Administrator, within sixty days, determines that a revised or new standard meets the requirements of this Act, it shall thereafter be the water quality standard for the applicable waters of that State. If the Administrator determines that any such standard is not consistent with this Act, he shall, within 90 days, notify the State and specify the changes to meet such requirement. If such changes are not adopted by the State, the Administrator shall promulgate such standard pursuant to paragraph (4) below.

(4) The Administrator shall promptly prepare and publish proposed regulations setting forth a revised or new water quality standard for the navigable waters involved —

(A) if a revised or new water quality standard submitted by such State for such waters is determined not to be consistent with this Act, or

(B) in any case where the Administrator determines that a revised or new standard is necessary to meet the requirements of this Act...

II

(d) (1) (A) Each State shall identify those waters within its boundaries for which the effluent limitations required by subparagraph 301(b)(1)(A) and subparagraph 301(b)(1)(B) are not stringent enough to implement any water quality standard

applicable to such waters. The State shall establish a priority ranking for such waters, taking into account the severity of the pollution and the uses to be made of such waters...

INFORMATION AND GUIDELINES

II SEC. 304...

(a) (1) The Administrator shall develop and publish, within one year, and periodically revise, criteria for water quality accurately reflecting the latest scientific knowledge (A) on the kind and extent of all identifiable effects on health and welfare including, but not limited to, plankton, fish, shellfish, wildlife, plant life, shorelines, beaches, esthetics, and recreation which may be expected from the presence of pollutants in any body of water, including ground water; (B) on the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes; and (C) on the effects of pollutants on biological community diversity, productivity, and stability, including information on the factors affecting rates of eutrophication and rates of organic and inorganic sedimentation for varying types of receiving waters.

(2) The Administrator shall develop and publish, within one year, and periodically revise, information (A) on the factors necessary to restore and maintain the chemical, physical, and biological integrity of all navigable waters, ground waters, waters of the contiguous zone, and the oceans; (B) on the factors necessary for the protection and propagation of shellfish, fish, and wildlife for classes and categories of receiving waters and to allow recreational activities in and on the water; (C) on the measurement and classification of water quality; and (D) for the purpose of section 303 [water quality standards and implementation plans] on and the identification of pollutants suitable for maximum daily load measurement correlated with the achievement of water quality objectives.

(3) Such criteria and information and revisions shall be issued to the States, published in the Federal Register and otherwise made available to the public.

(b) For the purpose of adopting or revising effluent limitations under this Act the Administrator shall publish and review at least annually, regulations, providing guidelines for effluent limitations. Such regulations shall --

(1) (A) identify, in terms of amounts of constituents and chemical, physical, and biological characteristics of pollutants, the degree of effluent reduction attainable through the application of the best practicable control technology currently available for classes and categories of point sources (other than publicly owned treatment works); and

(B) specify factors to be considered when determining the control measures and practices to be applicable to point sources (other than publicly owned treatment works) within such categories or classes. Factors relating to the assessment of best practicable control technology currently available to comply with subsection 301(b)(1) [1977 requirements] shall include consideration of the total cost of application of technology in relation to the effluent reduction benefits to be achieved and shall also take into account the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, non-water quality environmental impact (including energy requirements), and such other factors as the Administrator deems appropriate;

(2) (A) identify, in terms of amounts of constituents and chemical, physical, and biological characteristics of pollutants, the degree of effluent reduction attainable through the application of the best control measures and practices achievable including treatment techniques, process and procedure innovations, operating methods, and other alternatives for classes and categories of point sources (other than publicly owned treatment works); and

(B) specify factors to be considered when determining the best measures and practices available to comply with subsection 301(b)(2) [1983 - 1987 requirements] to be applicable to any point source (other than publicly owned treatment works) within such categories [or] classes. Factors relating to the assessment of best available technology shall take into account the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, the cost of achieving such effluent reduction, non-water quality environmental impact (including energy requirements), and such other factors as the Administrator deems appropriate;

(3) identify control measures and practices available to eliminate the discharge of pollutants from categories and classes of point sources, taking into account the cost of achieving such elimination of the discharge of pollutants; and ...

(c) The Administrator shall issue to the States and appropriate water pollution control agencies [before July 1973] (and from time to time thereafter) information on the processes, procedures, or operating methods which result in the elimination or reduction of the discharge of pollutants necessary to achieve standards of performance under section 306 of this Act. Such information shall include technical and other data, including costs, as are available on alternative methods of elimination or reduction of the discharge of pollutants. Such information, and revisions shall be published in the Federal Register and otherwise made available to the public...

(e) The Administrator may publish regulations for any specific pollutant which he is charged with a duty to regulate as a toxic or hazardous pollutant under section 307(a)(1) [toxic and pretreatment effluent standards] or 311 [oil and hazardous substance liability] of this Act, to control plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage which the Administrator determines are associated with or ancillary to the industrial manufacturing or treatment process within such class or category of point sources and may contribute significant amounts of such pollutants to navigable waters. Any applicable controls established under this subsection shall be included as a requirement for the purposes of section 301, 302, 306, 307, or 403, as the case may be, in any permit issued to a point source pursuant to section 402 of this Act [national pollutant discharge elimination].

(f) The Administrator shall issue, to appropriate Federal agencies, the States, water pollution control agencies, and agencies designated under section 208, before October 1973 and periodically thereafter, information including (1) guidelines for identifying and evaluating the nature and extent of nonpoint sources of pollutants, and (2) processes, procedures, and methods to control pollution resulting from ---

(A) agricultural and silvicultural activities, including runoff from fields and crop and forest lands;

(B) mining activities, including runoff and siltation from new, currently operating, and abandoned surface and underground mines;...

(D) the disposal of pollutants in wells or in subsurface excavations; ...

Such information and revisions shall be published in the Federal Register and otherwise made available to the public.

(g) (1) For the purpose of assisting States in carrying out programs under section 402 [national pollutant discharge elimination], the Administrator shall publish and review or revise

at least annually, guidelines for pretreatment of pollutants which he determines are not susceptible to treatment by publicly owned treatment works. Guidelines under this subsection shall be established to control and prevent the discharge into the navigable waters, the contiguous zone, or the ocean (either directly or through publicly owned treatment works) of any pollutant which interferes with, passes through, or otherwise is incompatible with such works...

(h) The Administrator shall promulgate guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to section 401 [certification] or permit application pursuant to section 402 [national pollutant discharge elimination].

(i) The Administrator shall (1) promulgate guidelines for the purpose of establishing uniform application forms and other minimum requirements for the acquisition of information from owners and operators of point sources of discharge subject to any State program under section 402 of this Act, and (2) ... promulgate guidelines establishing the minimum procedural and other elements of any State program under section 402 of this Act which shall include:

(A) monitoring requirements;

(B) reporting requirements (including procedures to make information available to the public);

(C) enforcement provisions; and

(j) The Administrator shall issue information biennially on methods, procedures, and processes to restore and enhance the quality of the Nation's publicly owned freshwater lakes.

(k) (1) The Administrator shall enter into agreements with the Secretary of Agriculture, the Secretary of the Army, and the Secretary of the Interior, and the heads of such other departments, agencies, and instrumentalities of the United States as he determines, to provide for maximum utilization of other Federal laws and programs for the purpose of achieving and maintaining water quality through appropriate implementation of plans approved under section 208 [areawide waste treatment management]...

WATER QUALITY INVENTORY

XII
II

SEC. 305...

(b) (1) Each State shall prepare and submit to the Administrator by April 1, 1975, and shall bring up to date by April 1, 1976, and biennially thereafter, a report which shall include --

(A) a description of the water quality of all navigable waters in such State during the preceding year, with appropriate supplemental descriptions as shall be required to take into account seasonal, tidal, and other variations, correlated with the quality of water required by the objective of this Act and the water quality described in subparagraph (B) of this paragraph;

(B) an analysis of the extent to which all navigable waters of such State provide for the protection and propagation of a balanced population of shellfish, fish, and wildlife, and allow recreational activities in and on the water;...

(D) an estimate of (i) the environmental impact, (ii) the economic and social costs necessary to achieve the objective of this Act in such State, (iii) the economic and social benefits of such achievement, and (iv) an estimate of the date of such achievement; and

(E) a description of the nature and extent of non-point sources of pollutants, and recommendations as to the programs which must be undertaken to control each category of such sources, including an estimate of the costs of implementing such programs.

(2) The Administrator shall transmit such State reports, together with an analysis of them, to Congress on or before October 1, 1975, and October 1, 1976, and biennially thereafter.

NATIONAL STANDARDS OF PERFORMANCE

II SEC. 306.

(a) For purposes of this section:

XVI (1) "Standard of performance" means a standard for the control of the discharge of pollutants which reflects the greatest degree of effluent reduction which the Administrator determines to be achievable through application of the best available demonstrated control technology, processes, operating methods, or other alternatives, including, where practicable, a standard permitting no discharge of pollutants.

XVI (2) "New source" means any source, the construction of which is commenced after the publication of proposed regulations prescribing a standard of performance under section which will be applicable to such source, if such standard is thereafter promulgated in accordance with this section.

XVI

(3) "Source" means any building, structure facility, or installation from which pollutants are or may be discharged.

(b) (1) (A) The Administrator shall publish (and from time to time thereafter shall revise) a list of categories of sources, which shall, at the minimum, include:

pulp and paper mills; ...
textile mills; ...
electroplating;
organic chemicals manufacturing;
inorganic chemicals manufacturing;
plastic and synthetic materials manufacturing;
soap and detergent manufacturing;
fertilizer manufacturing;
petroleum refining; ...
nonferrous metals manufacturing;
phosphate manufacturing; ...
ferroalloy manufacturing;
leather tanning and finishing;
glass and asbestos manufacturing;
rubber processing; and
timber products processing.

(B) As soon as practicable, but in no case more than one year after a category of sources is included in the list, the Administrator shall propose and publish regulations establishing Federal standards of performance for new sources within such category. The Administrator shall afford interested persons an opportunity for written comment on such proposed regulations. After considering such comments, he shall promulgate (within one hundred and twenty days after proposal) final standards. The Administrator shall, as technology and alternatives change, revise such standards following the procedure required by this subsection for initial promulgation. In establishing or revising Federal standards of performance for new sources under this section, the Administrator shall take into consideration the cost of achieving such effluent reduction, and any non-water quality environmental impact and energy requirements.

(2) The Administrator may distinguish among classes, types, and sizes within categories of new sources for the purpose of establishing such standards and shall consider the type of process employed (including whether batch or continuous).

TOXIC AND PRETREATMENT EFFLUENT STANDARDS

II

SEC. 307.

(a) (1) On and after the date of enactment of the Clean Water Act of 1977, the list of toxic pollutants or combinations of pollutants subject to this Act shall consist of those toxic pollutants listed below:

Acenaphthene
 Acrolein
 Acrylonitrile
 Aldrin/Dieldrin
 Antimony and compounds
 Arsenic and compounds
 Asbestos
 Benzene
 Benzidine
 Beryllium and compounds
 Cadmium and compounds
 Carbon tetrachloride
 Chlordane (technical mixture and metabolites)
 Chlorinated benzenes (other than dichlorobenzenes)
 Chlorinated ethanes (including 1,2-dichloroethane, 1,1,1-trichloroethane, and hexachloroethane)
 Chloroalkyl ethers (chloromethyl, chloroethyl, and mixed ethers)
 Chlorinated naphthalene
 Chlorinated phenols (other than those listed elsewhere; includes trichlorophenols and chlorinated cresols)
 Chloroform
 2-chlorophenol
 Chromium and compounds
 Copper and compounds
 Cyanides
 DDT and metabolites
 Dichlorobenzenes (1,2-, 1,3-, and 1,4-dichlorobenzenes)
 Dichlorobenzidine
 Dichloroethylenes (1,1- and 1,2-dichloroethylene)
 2,4-dichlorophenol
 Dichloropropane and dichloropropene
 2,4-dimethylphenol
 Dinitrotoluene
 Diphenylhydrazine
 Endosulfan and metabolites
 Endrin and metabolites
 Ethylbenzene
 Fluoranthene
 Haloethers (other than those listed elsewhere; includes chlorophenylphenyl ethers, bromophenylphenyl ether, bis(dichloroisopropyl) ether, bis-(chloroethoxy) methane and polychlorinated diphenyl ethers)

Halomethanes (other than those listed elsewhere;
includes methylene chloride, methylchloride,
methylbromide, bromoform, dichlorobromomethane,
trichlorofluoromethane, dichlorodifluoromethane)
Heptachlor and metabolites
Hexachlorobutadiene
Hexachlorocyclohexane (all isomers)
Hexachlorocyclopentadiene
Isophorone
Lead and compounds
Mercury and compounds
Naphthalene
Nickel and compounds
Nitrobenzene
Nitrophenols (including 2,4-dinitrophenol,
dinitrocresol)
Nitrosamines
Pentachlorophenol
Phenol
Phthalate esters
Polynuclear aromatic hydrocarbons (including
benzanthracenes, benzopyrenes, benzofluoranthene,
chrysenes, dibenzanthracenes, and indenopyrenes)
Selenium and compounds
Silver and compounds
2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)
Tetrachloroethylene
Thallium and compounds
Toluene
Toxaphene
Trichloroethylene
Vinyl chloride
Zinc and compounds

The Administrator may revise the list and is authorized to add to or remove any pollutant from the list. In publishing any revised list, the Administrator shall take into account the toxicity of the pollutant, its persistence, degradability the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms, and the nature and extent of the effect of the toxic pollutant on such organisms.

(2) Each toxic pollutant listed in accordance with paragraph (1) above shall be subject to effluent limitations achievable by application of the best available technology economically achievable for the applicable category or class of point sources established in accordance with sections 301(b)(2)(A) [effluent limitations; 1983-1987 requirements] and 304(b)(2) [information and guidelines]. [For each toxic pollutant the Administrator includes on the list, he shall establish effluent limitations as provided below. In his discretion, the Administrator may, in addition, propose an effluent

standard for any toxic pollutant on the list, which standard shall supersede any effluent limitations for those categories or classes of sources for which the standards are more stringent than the limitations.] Such published effluent standard (or prohibition) shall take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms, and the extent to which effective control is being or may be achieved under other regulatory authority. The Administrator shall allow a period of not less than sixty days following publication of any such proposed effluent standard (or prohibition) for written comment. In addition, if any interested person requests, the Administrator shall hold a public hearing. Such a public hearing shall provide an opportunity for oral and written presentations, such cross-examination as the Administrator determines is appropriate and the transcription of a verbatim record which shall be available to the public. After consideration of such comments and any information and material presented at any public hearing held on such proposed standard or prohibition, the Administrator shall promulgate final standards (or prohibition). Such promulgation shall be within two hundred and seventy days after proposal. Effluent limitations shall be established in accordance with sections 201(b)(2)(A) and 304(b)(2) for every toxic pollutant listed above by the Committee on Public Works and Transportation of the House as soon as practicable after the date of enactment of the Clean Water Act 1977, but no later than July 1, 1980. Effluent limitations or effluent standards (or prohibitions) shall be established for every other toxic pollutant listed under paragraph (1) of this subsection as soon as practicable after it is listed.

(3) Each such effluent standard (or prohibition) shall be reviewed and, if appropriate, revised at least every three years.

(4) Any effluent standard promulgated under this section shall be at that level which the Administrator determines provides an ample margin of safety...

(7) Prior to publishing any regulations pursuant to this section the Administrator shall, to the maximum extent practicable within the time provided, consult with appropriate advisory committees, States, independent experts, and Federal departments and agencies.

(b) (1) The Administrator shall before April 18, 1973, and from time to time thereafter, publish proposed regulations establishing pretreatment standards for introduction of pollutants into publicly owned treatment works for those pollutants which are determined not to be susceptible to treatment by such treatment works or which

would interfere with the operation of such treatment works. Pretreatment standards under this subsection... shall be established to prevent the discharge of any pollutant through treatment works which are publicly owned, which pollutant interferes with, passes through, or otherwise is incompatible with such works....

(c) In order to insure that any source introducing pollutants into a publicly owned treatment works (which source would be a new source and subject to section 306 if it were to discharge such pollutants) will not cause a violation of the effluent limitations established for any such treatment works, the Administrator shall promulgate pretreatment standards for the category of such sources simultaneously with the promulgation of standards of performance under section 306 for the equivalent category of new sources. The pretreatment standards shall prevent the discharge into such treatment works, of any pollutant which may interfere with, pass through, or otherwise be incompatible with such works...

INSPECTIONS, MONITORING, AND ENTRY

SEC. 308.

(a) Whenever required to carry out the objective of this Act, including but not limited to (1) developing or assisting in the development of any effluent limitation, or other limitation, prohibition, or effluent standard, pretreatment standard, or standard of performance under this Act; (2) determining whether any person is in violation of any such effluent limitation, or other limitation, prohibition or effluent standard, pretreatment standard, or standard of performance; (3) any requirement established under this section; or (4) carrying out sections 305, 311, 402, 404 (relating to State permit programs), and 504 (emergency powers) --

VII (A) the Administrator shall require the owner or
VI operator of any point source to (i) establish and maintain
XII such records, (ii) make such reports, (iii) install, use, and
V maintain such monitoring equipment or methods, (iv) sample
XIII such effluents (in accordance with such methods, at such
locations, at such intervals, and in such manner as the
Administrator shall prescribe), and (v) provide such information as he may reasonably require; and

VIII (B) the Administrator or his authorized representative,
upon presentation of his credentials --

(1) shall have a right of entry to, upon, or through any premises in which an effluent source is located or in which any records required to be maintained under clause (A) above are located, and

(11) may at reasonable times have access to and copy any records, inspect any monitoring equipment or method required under clause (A), and sample any effluents which the owner or operator of such source is required to sample under such clause.

XIV

(b) Any records, reports, or information obtained under this section (1) shall, in the case of effluent data, be related to any applicable effluent limitations, toxic, pretreatment, or new source performance standards, and (2) shall be available to the public, except that upon a showing satisfactory to the Administrator by any person that records, reports, or information, or particular part thereof (other than effluent data), to which the Administrator has access under this section, if made public would divulge methods or processes entitled to protection as trade secrets of such person, the Administrator shall consider such record, report, or information, or particular portion thereof confidential in accordance with the purposes of section 1905 of title 18 of the United States Code, except that such record, report, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out this Act or when relevant in any proceeding under this Act.

XVII

(c) Each State may develop and submit to the Administrator procedures under State law for inspection, monitoring, and entry with respect to point sources located in such State. If the Administrator finds that the procedures and the law of any State relating to inspection, monitoring, and entry are applicable to at least the same extent as those required by this section, such State is authorized to apply and enforce its procedures for inspection, monitoring, and entry with respect to point sources located in such State (except with respect to point sources owned or operated by the United States).

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OIL AND HAZARDOUS SUBSTANCE LIABILITY

SEC. 311.

(a) For the purpose of this section:

XVI

(1) "Oil" means oil of any kind or in any form, including, but not limited to, petroleum, fuel oil, sludge, oil refuse, and oil mixed with wastes other than dredged spoil; ...

(14) "Hazardous substance" means any substance designated pursuant to subsection (b)(2) below; ...

II (b) (1) The Congress declares that it is the policy of the United States that there should be no discharges of oil or hazardous substances into the navigable waters of the United States, adjoining shorelines, or into or upon the waters of the contiguous zone, or in connection with activities under the Outer Continental Shelf Lands Act or the Deepwater Port Act of 1974, or which may affect natural resources belonging to or under the exclusive management authority of the United States.

XI (2) (A) The Administrator shall develop, promulgate and revise as may be appropriate, regulations designating as hazardous substances, other than oil, such elements and compounds which, when discharged in any quantity into or upon the navigable waters of the United States or adjoining shorelines or the waters of the contiguous zone... present an imminent and substantial danger to the public health or welfare, including, but not limited to, fish, shellfish, wildlife, shorelines, and beaches.

(B) (i) The Administrator shall include in any designation under subparagraph (A) of this subsection a determination whether any such designated hazardous substance can actually be removed...

(3) The discharge of oil or hazardous substances into or upon the navigable waters of the United States, adjoining shorelines, or into or upon the waters of the contiguous zone ... in harmful quantities as determined by the President under paragraph (4) below is prohibited except ...

(4) The President shall by regulation determine for the purposes of this section, those quantities of oil and any hazardous substance the discharge of which, at such times, locations, circumstances, and conditions, will be harmful to the public health or welfare of the United States, including but not limited to, fish, shellfish, wildlife, public and private property, shorelines, and beaches.

(5) Any person in charge of a vessel or of an onshore facility or an offshore facility shall, as soon as he has knowledge of any prohibited discharge of oil or a hazardous substance, immediately notify the appropriate agency of the United States Government of such discharge. Any such person who fails to immediately notify such agency of such discharge shall, upon conviction, be fined not more than \$10,000, or imprisoned for not more than one year, or both. Notification received pursuant to this paragraph or information obtained by the exploitation of such notification shall not be used against any such person in any criminal case, except a prosecution for perjury or for giving a false statement...

(c) (2) ... the President shall prepare and publish a National Contingency Plan for removal of oil and hazardous substances which shall provide for efficient, coordinated, and effective action to minimize damage from oil and hazardous substance discharges, including containment, dispersal, and removal of oil and hazardous substances, and shall include, but not be limited to -- ...

(D) a system of surveillance and notice designed to insure earliest possible notice of discharges of oil and hazardous substances and imminent threats of such discharges to the appropriate State and Federal agencies;...

(m) Anyone authorized by the President to enforce the provisions of this section may, except as to public vessels, (A) board and inspect any vessel upon the navigable waters of the United States or the waters of the contiguous zone,... and (C) execute any warrant or other process issued by an officer or court of competent jurisdiction.

* * *

TITLE IV -- PERMITS AND LICENSES

CERTIFICATION

SEC. 401.

X (a) (1) Any applicant for a Federal license or permit to conduct any activity including the construction or operation of facilities, which may result in any discharge into the navigable waters, shall provide the licensing or permitting agency a certification from the State in which the discharge originates or will originate, (or, if appropriate, from the interstate water pollution control agency having jurisdiction over the navigable waters at the point where the discharge originates or will originate) that any such discharge will comply with the applicable provisions of section 301 [effluent limitations], 302, 303 [water quality standards and implementation plans], and 307 [toxic and pretreatment effluent standards]. In the case of any activity for which there is not an applicable effluent limitation or standard, the State shall so certify. Such State or interstate agency shall establish procedures for public notice and hearings in the case of applications for certification. No license or permit shall be granted until the certification required by this section has been obtained or has been waived. No license or permit shall be granted if certification has been denied by the State, interstate agency, or the Administrator.

IV

(2) Upon receipt of an application and certification the licensing or permitting agency shall immediately notify the Administrator. Whenever such a discharge may affect, as determined by the Administrator, the quality of the waters of any other State, the Administrator shall notify such other State, the licensing or permitting agency, and the applicant within 30 days. If, such other State determines that the discharge will affect the quality of its waters so as to violate any water quality requirement in such State, and within sixty days notifies the Administrator and the licensing or permitting agency in writing of its objection to the issuance of such license or permit and requests a public hearing on such objection, the licensing or permitting agency shall hold such a hearing. The Administrator shall at such hearing submit his evaluation and recommendations with respect to any such objection to the licensing or permitting agency. Such agency, based upon the recommendations of such State, the Administrator, and upon any additional evidence, if any, shall condition such license or permit in such manner as may be necessary to insure compliance with applicable water quality requirements. If the imposition of conditions cannot insure such compliance such agency shall not issue such license or permit...

IV

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(b) ... The Administrator shall, upon the request of any Federal department or agency, or State, or interstate agency, or applicant, provide, for the purpose of this section, any relevant information on applicable effluent limitations, or other limitations, standards, regulations, or requirements, or water quality criteria, and shall, when requested by any such department, or agency, or State, or interstate agency, or applicant, comment on any methods to comply with such limitations, standards, regulations, requirements, or criteria...

V

(d) Any certification provided under this section shall set forth any effluent limitations and other limitations and other monitoring requirements necessary to assure that any applicant for a Federal license or permit will comply with any applicable effluent limitations and other limitations, under section 301 or 302, standard of performance under section 306, or prohibition, effluent standard, or pretreatment standard under section 307, and with any other appropriate requirement of State law set forth in such certification, and shall become a condition on any Federal license or permit subject to the provisions of this section.

NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

X SEC. 402.

(a) (1) Except as provided in sections 318 and 404 of this Act, the Administrator may, after opportunity for public hearing,

issue a permit for the discharge of any pollutant, or combination of pollutants, notwithstanding section 301(a), upon condition that such discharge will meet either all applicable requirements under sections 301, 302, 306, 307, 308, and 403 of this Act, or such conditions as the Administrator determines are necessary to carry out the provisions of this Act.

VII (2) The Administrator shall prescribe conditions for such permits to assure compliance with the requirements of paragraph (1) above, including conditions on data and information collection, reporting and such other requirements as he deems appropriate.

(3) The permit program of the Administrator under paragraph (1) above, and permits issued thereunder, shall be subject to the same terms, conditions, and requirements as apply to a State permit program...

XVII (b) At any time after the promulgation of the guidelines for State programs (required by subsection (h)(2) of section 304), the Governor of each State desiring to administer its own permit program may submit a full and complete description of the program it proposes. The Administrator shall approve each such submitted program unless he determines that adequate legal authority does not exist:

(1) To issue permits which --

(A) apply, and insure compliance with, any applicable requirements of sections 301, 302, 306, 307, and 402;

(B) are for fixed terms not exceeding five years; ...

(D) control the disposal of pollutants into wells;

(2) (A) To issue permits which apply, and insure compliance with, all applicable requirements of section 308 (inspections, monitoring and entry), or

(B) To inspect, monitor, enter, and require reports to at least the same extent as required in section 308 of this Act; ...

(4) To insure that the Administrator receives notice and a copy of each application for a permit;...

(8) To insure that any permit for a publicly owned treatment works includes conditions to require the identification of pollutants introduced by any significant source subject to pretreatment standards and a program to assure compliance with such pretreatment standards. In addition, adequate notice shall be required (to the permitting agency) of (A) new introductions of pollutants from any source which would be a "new" source if it were discharging pollutants, (B) new introductions of pollutants into such works from a source which would be subject to section 301

XI

if it were discharging such pollutants, or (C) a substantial change in volume or character of pollutants, being introduced into such works. Such notice shall include information on the quality and quantity of effluent to be introduced and any anticipated impact of such change on the quantity or quality of effluent to be discharged from such publicly owned treatment works; and

(9) To insure that any industrial user of any publicly owned treatment works will comply with sections 204(b) [User Charges by Treatment Works], 307 [Toxic and Pretreatment Effluent Standards], and 308 [Inspections, Monitoring and Entry]...

XI. (d) (1) Each State shall transmit to the Administrator a copy of each permit application received and provide notice to the Administrator of every action related to the consideration of such permit application, including each permit proposed to be issued.

(2) No permit shall issue (A) if the Administrator objects in writing, within ninety days, to the issuance of such permit, or (B) if the Administrator within ninety days of the date of transmittal of the proposed permit by the State objects in writing to the issuance of such permit as being outside the guidelines and requirements of this Act. Whenever the Administrator objects to the issuance of a permit under this paragraph, such written objection shall contain a statement of the reasons for such objection and the effluent limitations and conditions which such permit would include if it were issued by the Administrator...

(j) A copy of each permit application and each permit issued under this section shall be available to the public. Such permit application or permit, or portion thereof, shall be available on request for the purpose of reproduction.

OCEAN DISCHARGE CRITERIA

II SEC. 403.

X (a) No permit under section 402 [National Pollutant Discharge Elimination System] of this Act for a discharge into the territorial sea, the waters of the contiguous zone, or the oceans shall be issued, after promulgation of guidelines established under subsection (c) below except in compliance with such guidelines.

(b) The requirements of subsection 402(d) may not be waived in the case of permits for discharges into the territorial sea.

(c) (1) The Administrator shall, by April 1973 (and from time to time thereafter), promulgate guidelines for determining the degradation of the waters of the territorial seas, the contiguous zone, and the oceans, which shall include:

(A) the effect of disposal of pollutants on human health or welfare including but not limited to plankton, fish, shellfish, wildlife, shorelines, and beaches;

(B) the effect of disposal pollutants on marine life including the transfer, concentration, and dispersal of pollutants or their byproducts through biological, physical, and chemical processes; changes in marine ecosystem diversity, productivity, and stability; and species and community population changes;

(C) the effect of disposal of pollutants on esthetic, recreation, and economic values;

(D) the persistence and permanence of the effects of disposal of pollutants;

(E) the effect of the disposal at varying rates, of particular volumes and concentrations of pollutants;

(F) other possible locations and methods of disposal or recycling of pollutants including land-based alternatives; and

(G) the effect on alternate uses of the oceans, such as mineral exploitation and scientific study.

(2) In any event, where insufficient information exists on any proposed discharge to make a reasonable judgment on any of the guidelines established pursuant to this subsection, no permit shall be issued.

[SEC. 404 establishes a permit program to deal with dredged or fill material. This was deemed insufficiently related to toxic substances regulation to be included in the compendium.]

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TITLE V -- GENERAL PROVISIONS

ADMINISTRATION

SEC. 501.

VII

(a) The Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this Act.

- III (b) The Administrator, with the consent of the head of any other agency of the United States, may utilize such officers and employees of such agency as may be found necessary to assist in carrying out the purposes of this Act...

GENERAL DEFINITIONS

SEC. 502.

Except as otherwise specifically provided, when used in this Act:...

- XVI (11) "Effluent limitation" means any restriction established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the oceans, including schedules of compliance...
- XVI (13) "Toxic pollutant" means those pollutants or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring...
- XVI (15) "Biological monitoring" shall mean the determination of the effects on aquatic life (including accumulation of pollutants in tissue) in receiving waters due to the discharge of pollutants (A) by techniques and procedures (including sampling of organisms representative of appropriate levels of the food chain) appropriate to the volume and the physical, chemical, and biological characteristics of the effluent, and (B) at appropriate frequencies and locations...
- XVI (18) "Industrial user" means those industries identified in the Standard Industrial Classification Manual, Bureau of the Budget, 1967, as amended and supplemented, under the category "Division D Manufacturing" and such other classes of significant waste producers as, by regulation, the Administrator deems appropriate.
- XVI (19) "Pollution" means the man-made or man-induced alteration of the chemical, physical, biological, and radiological integrity of water.

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ADMINISTRATIVE PROCEDURE AND JUDICIAL REVIEW

SEC. 509.

IX (a) (1) For purposes of obtaining information under section 305 [water quality inventory]... the Administrator may issue subpoenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and he may administer oaths.

XIV Except for effluent data, upon a showing satisfactory to the Administrator that such papers, books, documents, or information or particular part thereof, if made public, would divulge trade secrets or secret processes, the Administrator shall consider such record, report, or information or particular portion thereof confidential in accordance with the purposes of section 1905 of title 18 of the United States Code, except that such paper, book, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out this Act, or when relevant in any proceeding under this Act.

IX (2) The district courts of the United States are authorized, upon application by the Administrator, to issue subpoenas for attendance and testimony of witnesses and the production of relevant papers, books, and documents, for purposes of obtaining information under subsections 304(b) [adopting or revising effluent limitations] and (c) [developing information on processes, procedures and operating methods] of this Act. Any papers, books, documents or other information or part thereof, obtained by reason

XIV of such a subpoena, shall be subject to the same [confidentiality] requirements as are provided in paragraph (1) above...

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EFFLUENT STANDARDS AND WATER QUALITY INFORMATION ADVISORY COMMITTEE

IV SEC. 515.

[The Effluent Standards and Water Quality Information Advisory Committee is currently not active and there are no plans to make use of the Committee in the future. This section of FWPCA is, therefore, not contained in the compendium.]

REPORTS TO CONGRESS

II SEC. 516.

(a) Within ninety days following the convening of each session of Congress, the Administrator shall submit to the Congress a report, in addition to any other report required by this Act, on measures taken toward implementing the objective of this Act, including, but not limited to, ... (2) a summary of actions taken and results achieved in the field of water pollution control research, experiments, studies, and related matters by the Administrator and other Federal agencies and by other persons and agencies under Federal grants or contracts; (3) the progress and problems associated with the development of effluent limitations and recommended control techniques; ... (7) a summary of the results of the survey required to be taken under section 210 of this Act, ...

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PUBLIC LAW 93-523 -- December 16, 1974
as amended by
PUBLIC LAW 95-190 -- November 16, 1977

"SAFE DRINKING WATER ACT"

Part A -- DEFINITIONS

SEC. 1401.

For purposes of this title:

- XVI (1) "Primary drinking water regulation" means a regulation which --
- (A) applies to public water systems;
 - (B) specifies contaminants which, may have an adverse effect on human health;
 - (C) specifies for each such contaminant either --
 - (i) a maximum contaminant level, or
 - (ii) each treatment technique which reduces the level of the contaminant sufficiently to satisfy the requirements of section 1412 below; and
 - (D) contains criteria and procedures to assure a supply of drinking water which dependably complies with maximum contaminant levels.
- XVI (2) "Secondary drinking water regulation" means a regulation which applies to public water systems and which specifies the maximum contaminant levels which are requisite to protect the public welfare. Such regulations may apply to which may adversely affect the odor or appearance of such water or which may otherwise adversely affect the public welfare.
- XVI (3) "Maximum contaminant level" means the maximum permissible level of a contaminant in water is delivered to any user of a public water system.

PART B -- PUBLIC WATER SYSTEMS

NATIONAL DRINKING WATER REGULATIONS

II SEC. 1412...

- III (e) (1) The Administrator shall enter into appropriate arrangements with the National Academy of Sciences or other

independent scientific organization to conduct a study to determine (A) the maximum contaminant levels which could be recommended [for adoption as primary or secondary drinking water regulations] in order to protect the health of persons from any known or anticipated adverse effects, and (B) the existence of any contaminants the levels of which cannot be determined in drinking water but which may have an adverse effect on health.

(2) The result of the study shall be reported to Congress no later than December 16, 1976, and updated reports shall be sent to the Congress every two years. The report shall contain (A) a summary and evaluation of relevant publications and unpublished studies; (B) a statement of methodologies and assumptions for estimating the levels at which adverse health effects may occur; (C) a statement of methodologies and assumptions for estimating the margin of safety which should be incorporated in the national primary drinking water regulations; (D) proposals for recommended maximum contaminant levels for national primary drinking water regulations, based on the methodologies, assumptions, and studies referred to above and in paragraph (4) below; (E) a list of contaminants which cannot be measured in drinking water, but which may have an adverse effect on health; (F) recommended studies and test protocols for future research on the health effects of drinking water contaminants, including a list of the major research priorities and estimated costs necessary to conduct such priority research; (G) periodic assessments and evaluations of unregulated contaminants which may require continuous monitoring or regulation.

(3) In developing its proposals for recommended maximum contaminant levels the National Academy of Sciences (or other organization preparing the report) shall evaluate and explain the impact of the following considerations:

(A) The existence of groups or individuals in the population which are more susceptible to adverse effects than the normal healthy adult.

(B) The exposure to contaminants in other media than drinking water (including exposures in food, in the ambient air, and in occupational settings) and the resulting body burden of contaminants.

(C) Synergistic effects resulting from exposure to or interaction by two or more contaminants.

(D) The contaminant exposure and body burden levels which alter physiological function or structure in a manner reasonably suspected of increasing the risk of illness.

(4) In making the study under this subsection, the National Academy of Sciences (or other organization) shall collect and correlate (A) morbidity and mortality data and (B) monitored data on the quality of drinking water. Any conclusions based on such correlations shall be included in the report of the study...

STATE PRIMARY ENFORCEMENT RESPONSIBILITY

SEC. 1413.

(a) For purposes of this title, a State has primary enforcement responsibility for public water systems during any period for which the Administrator determines that such State -- ...

V (2) has adopted and is implementing adequate procedures for
VIII the enforcement of such State regulations, including conducting
such monitoring and making such inspections as the Administrator
may require by regulation;

VI (3) will keep such records and make such reports with
respect to its activities under paragraphs (1) and (2) as the
Administrator may require by regulation;

PART C -- PROTECTION OF UNDERGROUND SOURCES OF DRINKING WATER

REGULATIONS FOR STATE PROGRAMS

SEC. 1421...

(b) (1) Regulations for State underground injection programs shall contain minimum requirements for effective programs to prevent underground injection which endangers drinking water sources. Such regulations shall require that a State program --

X (A) by December 16, 1974, prohibit any underground
injection which is not authorized by a permit issued by
the State (except that the regulations may permit a State to
authorize underground injection by rule);

(B) require (i) that an applicant for a permit to inject must satisfy the State that the underground injection will not endanger drinking water sources, and (ii) that no rule may be promulgated which authorizes any underground injection which endangers drinking water sources;

VIII
V VII

(C) include inspection, monitoring, record-keeping, and reporting requirements; and ...

(d) For purposes of this part:

XVI

(1) "Underground injection" means the subsurface emplacement of fluids by well injection.

XVI

(2) Underground injection endangers drinking water sources if such injection may result in the presence of any contaminant which may result in a drinking water system not complying with any national primary drinking water regulation or may otherwise adversely affect health.

STATE PRIMARY ENFORCEMENT RESPONSIBILITY

SEC. 1422...

X

(b) (1) (A) [An application for approval of a State's underground injection control program must include assurance that the State]...

VI

(ii) will keep such records and make such reports with respect to its activities under its underground injection control program as the Administrator may require by regulation...

* * *

PART E -- GENERAL PROVISIONS

RESEARCH, TECHNICAL ASSISTANCE, INFORMATION, AND TRAINING OF PERSONNEL

II

SEC. 1442.

(a) (1) The Administrator may conduct research, studies and demonstrations relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments of man resulting directly or indirectly from contaminants in water, or relating to the provision of a dependably safe supply of drinking water, including --

(A) improved methods (i) to identify and measure the existence of contaminants in drinking water, and (ii) to identify the source of such contaminants;

(B) improved methods to identify and measure the health effects of contaminants in drinking water; ... and

(E) improved methods of protecting underground water sources of public water systems from contamination.

III

(2) (A) The Administrator shall, to the maximum extent feasible, provide technical assistance to the States and municipalities in the establishment and administration of public water system supervision programs...

(4) The Administrator shall conduct a survey and study of --

(A) disposal of waste (including residential waste) which may endanger underground water which supplies, or can reasonably be expected to supply, any public water system, and

(B) means of control of such waste disposal.

Not later than December 16, 1975, he shall transmit to the Congress the results of such survey and study, together with such recommendations as he deems appropriate.

(5) The Administrator shall carry out a study of methods of underground injection which do not result in the degradation of underground drinking water sources.

(6) The Administrator shall carry out a study of methods of preventing, detecting, and dealing with surface spills of contaminants which may degrade underground water sources for public water systems...

(8) The Administrator shall carry out a study of the nature and extent of the impact on underground water supplies of (A) abandoned injection or extraction wells; (B) intensive application of pesticides and fertilizers in underground water recharge areas; and (C) ponds, pools, lagoons, pits, or other surface disposal of contaminants in underground water recharge areas...

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RECORDS AND INSPECTIONS

SEC. 1445.

VII
V

(a) Every person who is a supplier of water who is subject to a primary drinking water regulation or to an applicable underground injection control program... shall establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation to assist him in establishing regulations under this title, in determining whether such person has acted or is acting in compliance with this title... in evaluating the health risks of unregulated contaminants, or in advising the public of such risks.

VIII

(b) (1) Except as provided in paragraph (2), the Administrator, or his representative, upon presenting appropriate credentials and a written notice to any supplier of water or other person subject to (A) a national primary drinking water regulation, (B) an applicable underground injection control program, or (C) any requirement to monitor an unregulated contaminant pursuant to subsection (a) above, is authorized to enter any establishment, facility, or other property of such supplier or other person in order to determine whether such person has acted or is acting in compliance with this title, including for this purpose, inspection, at reasonable times, of records, files, papers, processes, controls, and facilities, or in order to test any feature of a public water system, including its raw water source...

XIV

(d) (1) Subject to paragraph (2), upon a showing satisfactory to the Administrator by any person that any information required under this section from such person, if made public, would divulge trade secrets or secret processes of such person, the Administrator shall consider such information confidential in accordance with the purposes of section 1905 of title 18 United States Code. If the applicant fails to make a showing satisfactory to the Administrator, the Administrator shall give such applicant thirty days notice before releasing the information (unless the public health or safety requires earlier release of such information).

* * *

GENERAL PROVISIONS

VII

SEC. 1450.

(a) (1) The Administrator is authorized to prescribe such regulations as are necessary or appropriate to carry out his functions under this title...

* * *

[21 USC 301-392 -- As amended through October, 1976]

"FEDERAL FOOD, DRUG, AND COSMETIC ACT"

CHAPTER II -- DEFINITIONS

SEC. 201.

For the purposes of this Act -- ...

XVI (c) "Department" means the U.S. Department of Health, Education, and Welfare...

XVI (f) "Food" means (1) articles used for food or drink for man or other animals, (2) chewing gums, and (3) articles used for components of any such article.

XVI (g) (1) "Drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C), but does not include devices or their components, parts, or accessories. [Note: Devices are not considered in this compendium because of their lack of chemical action and concomitant non-toxic nature, ed.]...

XVI (i) "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as components of such articles, except that such term does not include soap.

XVI (j) "Official compendium" means the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them.

(k) "Label" means a display of written, printed, or graphic matter upon the immediate container of any article. Any information required under this Act to appear on a label shall appear on the outside container or wrapper or be easily legible through the outside container or wrapper...

XVI (m) "Labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.

XVI (n) In determining whether an article is misbranded because the labeling or advertising is misleading, the Secretary shall take into account (among other things) not only representations made or suggested by statement, word, design, or device or combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article as prescribed in the labeling or advertising or under customary or usual conditions of use...

XVI (p) "New drug" means —

(1) Any human drug which is not generally recognized, among qualified experts, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling, exclusive of any drug subject to the Food and Drugs Act of June 30, 1906, if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any human drug which, as a result of investigations to determine its safety and effectiveness, has become recognized as safe but which has not been extensively used.

XVI (q) "Pesticide chemical" means any substance which alone or in chemical combination or in formulation with one or more other substances is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act and which is used in the production, storage, or transportation of raw agricultural commodities.

XVI (r) "Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.

XVI (s) "Food additive" means any substance which may, as a result of its intended use, directly or indirectly, become a component of or otherwise affect the characteristics of any food (including any substance used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food if such substance is not generally recognized by qualified experts as safe under the conditions of its intended use; except that such term does not include —

(1) a pesticide chemical in or on a raw agricultural commodity;

(2) a pesticide chemical used in the production, storage, or transportation of any raw agricultural commodity;

(3) any color additive;

(4) any substance regulated under the Poultry Products Inspection Act or the Meat Inspection Act of March 4, 1907; or

(5) a new animal drug.

XVI

(t) (1) "Color additive" means --

(A) a dye, pigment, or other substance made by synthesis or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added to a food, drug, or cosmetic, or to the human body, is capable of imparting color and is used for such purpose.

(2) "Color" includes black, white, and intermediate grays.

XVI

(u) "Safe" as used in paragraph (s) above and in sections 409, 512, and 706, has reference to the health of man or animal...

CHAPTER III -- PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

XVII SEC. 301.

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise...

(e) The refusal to permit access to or copying of any record as required by section 703 [records of interstate shipment]; or the failure to establish or maintain any record, or make any report, required under section 505(i) or (j) [new drug research]; 507 (d) or (g) [batch certification of antibiotics], 512 (j), (l) or (m), 515 (f) or 519, or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 704 [factory inspection].

(g) The manufacture within any Territory of any food, drug, device or cosmetic that is adulterated or misbranded...

XIV (j) The (1) using by any person to his own advantage, or (2) revealing, other than to the Secretary or officers of the Department, or to the courts, of any information acquired under the authority of section 404, 409, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 704, 706, or 708 concerning any method or process which is a trade secret.

[The table below is not contained in the Act, but is put here for the convenience of the reader.]

Section 404	Emergency permit control
Section 409	Food additives
Section 505	New drugs
Section 506	Certification of drugs containing insulin
Section 507	Certification of antibiotics
Section 510	Registration of producers of drugs and devices
Section 512	New animal drugs
Section 513	Classification of devices intended for human use
Section 514	Performance standards
Section 515	Premarket approval
Section 516	Banned devices
Section 518	Notification and other remedies
Section 519	Records and reports on devices
Section 520	General provisions respecting control of devices intended for human use
Section 704	Factory inspection
Section 706	Listing and certification of color additives for foods, drugs, and cosmetics
Section 708	Confidential information

XV (o) The failure of any manufacturer, packer, or distributor of a prescription drug to maintain or transmit, to any licensed practitioner who makes written request for information about such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary.

(p) The failure to register in accordance with section 510, the failure to provide any information required by section 510(j) or 510(k), or the failure to provide a notice required by section 510(j)(2)...

[The subpoena authority in section 307 is not included because it does not accrue to the Secretary or the Administrator and because it is related to violation and enforcement actions rather than information development activities.]

* * *

CHAPTER IV -- FOOD

DEFINITIONS AND STANDARDS FOR FOOD

II SEC. 401.

Whenever, in the judgment of the Secretary, such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container ...

In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label ...

ADULTERATED FOOD

XVI SEC. 402.

A food shall be deemed to be adulterated --

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or

(2) (A) If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of such section 408(a); or (C) if it is or it bears or contains any food additive which is unsafe within the meaning of section 409: Provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with

an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity...; or

(3) If it consists, in whole or in part, of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth ... or whereby it may have been rendered injurious to health, ...; or ...

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health ...

(b) (1) If any valuable constituent has been, in whole or in part, omitted or abstracted therefrom; or

(2) If any substance has been substituted wholly or in part therefor; or

(3) If damage or inferiority has been concealed in any manner; or

(4) If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

(d) If it is confectionery, and —

(1) has partially or completely imbedded therein any non-nutritive object...;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts; or

(3) bears or contains any non-nutritive substance...;

MISBRANDED FOOD

XV

SEC. 403.

A food shall be deemed to be misbranded --

(a) If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 [vitamins and minerals] applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated...

(e) If in a package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon, with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed under section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food as specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food...

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each ingredient, except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: Provided, that, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical ...

* * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD

II SEC. 406.

Any poisonous or deleterious substance added to any food, except where required in the production thereof or unavoidable by good manufacturing practice, shall be deemed unsafe and the food deemed adulterated, but when such substance is required or cannot be avoided, the Secretary shall promulgate regulations limiting the quantity as he finds necessary for the protection of public health, and any greater quantity shall be deemed unsafe and the food deemed adulterated. While a regulation is in effect limiting the quantity of any substance in any food, such food shall not, by reason of containing any added amount of such substance, be considered adulterated. In determining the quantity of such added substance to be tolerated in different articles of food, the Secretary shall take into account the extent to which such substance is required or unavoidable in the production of such article, and any other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

* * *

TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

II SEC. 408...

(b) The Secretary* shall establish tolerances for use (in or on raw agricultural commodities) of poisonous or deleterious pesticide

*Responsibilities for establishing tolerances under this section were transferred by Executive Order to the Environmental Protection Agency.

chemicals and of pesticide chemicals which are not generally recognized by qualified experts as safe for use, to the extent necessary to protect the public health. The Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under this section. The Secretary may establish a tolerance at zero level if the scientific data before him do not justify the establishment of a greater tolerance.

(c) The Secretary shall exempt any pesticide chemical from the necessity of a tolerance when such a tolerance is not necessary to protect the public health.

X
XII (d) (1) Any person who has registered, or has applied for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may petition the Secretary, proposing establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of such economic poison, or proposing exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain --

(A) the name, chemical identity, and composition of the pesticide chemical;

I (B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

I (D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the chemical shall be furnished to the Secretary upon request. Notice of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the determination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

X

(2) Within ninety days after certification of usefulness by the Secretary of Agriculture the Secretary shall, by order make public a regulation --

(A) establishing a tolerance for the pesticide chemical,
or

(B) exempting the pesticide chemical from the necessity of a tolerance,

unless the person filing the petition requests or the Secretary decides that the petition should be referred to an advisory committee.

(3) If necessary, the Secretary shall submit the petition and any other data before him to an advisory committee. Not later than sixty days thereafter, the committee shall certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period may be extended by the advisory committee for an additional thirty days. Within thirty days, the Secretary shall then, by order, make public a regulation --

(A) establishing a tolerance for the pesticide chemical;
or

(B) exempting the pesticide chemical from the necessity of a tolerance...

(e) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical names in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g), below. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal together with all underlying

data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical names in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publication. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

XIV

(f) All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section.

(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal...

II

(j) The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act...

XI

(1) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registration of, a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such [a pesticide], shall, within thirty days, or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either --

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Secretary may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Secretary of Agriculture shall provide an opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection...

FOOD ADDITIVES

UNSAFE FOOD ADDITIVES

SEC. 409.

XVI

(a) A food additive shall, with respect to any particular use or intended use, be deemed unsafe and the food adulterated unless --

(1) the additive and its use conform to an exemption in effect pursuant to this section; or

(2) there is a regulation issued under this section prescribing the conditions under which such additive may be safely used and that regulation is complied with...

PETITION TO ESTABLISH SAFETY*

X (b) (1) Any person may file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain --

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effects such addition is intended to produce, and the quantity of such addition required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

XII (E) full reports of investigations made with respect to the safety of use of such additive, including full information on the methods and controls used in conducting such investigations.

V (3) Upon request of the Secretary, the manufacturer of such additive shall furnish a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used...

* EPA is responsible for establishing food additive regulations for pesticide chemicals when processing raw agricultural commodities results in concentration of pesticide residues.

ACTION ON THE PETITION

II (c) (1) The Secretary shall --

(A) by order establish a regulation prescribing [among other things]... any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use; or

(B) by order deny the petition...

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary --

(A) fails to establish that the proposed use of the food additive will be safe: Provided, that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of animals which are raised for food production if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to objections, public hearings or judicial review) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additives would promote deception or otherwise result in misbranding or adulteration.

(4) ... the Secretary --

(A) shall not fix a tolerance limitation at a level higher than required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds that the data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining whether a proposed use of a food additive is safe, the Secretary shall consider —

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which are generally recognized as appropriate for the use of animal experimentation data.

REGULATION ISSUED ON SECRETARY'S INITIATIVE

II (d) The Secretary may at any time, upon his own initiative, propose the conditions under which an additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon his proposal ...

IV (f) (1) ... any person adversely affected by an order under subsection (c) or (d) above, may request a hearing...

EXEMPTIONS FOR INVESTIGATIONAL USE

X (i) ... the Secretary shall provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

[SEC. 411, VITAMINS AND MINERALS, is omitted because of the improbability that these substances will ever be important in toxic substances regulation.]

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CHAPTER V -- DRUGS AND DEVICES*

ADULTERATED DRUGS AND DEVICES

XVI SEC. 501.

A drug or device shall be deemed to be adulterated --

(a) ...; (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; (4) if it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a) ...; (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) If it is a drug and its strength differs from, or its quality or purity falls below, the standards set forth in an official compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except when tests or methods as are prescribed are, in the judgment of the Secretary, insufficient for making such determination. In such case, the Secretary shall bring that fact to the attention of the body charged with the revision of such compendium. If such body fails to prescribe tests or methods of assay which are sufficient, the Secretary shall prescribe appropriate tests or methods of assay ...

MISBRANDED DRUGS AND DEVICES

XVI SEC. 502.
IX

A drug or device shall be deemed to be misbranded --

(a) If its labeling is false or misleading in any particular.

(b) If in a package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

* Because of their non-chemical nature and consequent non-toxic nature, most provisions dealing with or referring to devices are omitted from the compendium.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been, after investigation, found by the Secretary to be habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning -- May be habit-forming".

(e) (1) If it is a drug, unless (A) its label bears the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of such substances, contained therein...

(3) As used in subparagraph (1) "established name" means (A) the applicable official name designated pursuant to section 508, or (B) if such drug or ingredient is recognized in an official compendium, then the official title in such compendium, or (C) if neither (A) or (B) applies, then the common or usual name.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application; in such manner and form as are necessary for the protection of users ...

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein...

(j) If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof...

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NEW DRUGS

SEC. 505.

(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) below is effective with respect to such drug.

I (b) Any person may file with the Secretary an application with respect to any new drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and control used for the manufacture, processing, and packaging of such drug; (5) samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either --

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) below applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question of whether such application is approvable.

II (d) If the Secretary finds, after due notice and opportunity for a hearing that (1) the investigations do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) there is a lack of substantial evidence that the drug will have the

effect it purports or is represented to have; or (6) such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) below, "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations by experts on the basis of which it could fairly and responsibly be concluded by experts that the drug will have the effect it purports or is represented to have...

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(e) ...: Provided, that if the Secretary finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately ... The Secretary may also, after due notice to the applicant and opportunity for hearing, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j) or to comply with the notice requirements of paragraph 510(j)(2), or the applicant has refused to permit access to, or copying or verification of such records as required...

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(i) The Secretary shall by regulation exempt from this section drugs intended solely for investigational use by experts. Such regulations may (in the discretion of the Secretary) among other conditions, require —

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(1) submission (before any clinical testing of a new drug is undertaken) of reports of investigations or preclinical tests adequate to justify the proposed clinical testing;

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(2) obtaining a signed agreement from each investigator that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

VII

(3) establishment and maintenance of such records, and the making of such reports as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to section (b) above.

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Such regulations shall require investigators to certify to the sponsor that they will inform any human beings to whom such drugs or any controls are being administered (or their representatives), that such drugs are being used for investigational purposes, and that the consent

of such human beings (or their representatives) will be obtained except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.

VII

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(j) (1) In the case of any approved application, the applicant shall establish and maintain such records, and make such reports -- of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug -- as the Secretary may by general regulation, or by special order, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be grounds for invoking subsection (e) of this section [withdrawal or suspension of approval]...

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(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer designated by the Secretary, permit such officer at all reasonable times to have access to and to copy and verify such records.

[SEC. 506, CERTIFICATION OF DRUGS CONTAINING INSULIN, and SEC 507, CERTIFICATION OF ANTIBIOTICS, are omitted because of the improbability that these substances will ever be important in toxic substances regulation.]

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AUTHORITY TO DESIGNATE OFFICIAL NAMES

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SEC. 508.

(a) The Secretary may designate an official name for any drug or device if necessary or desirable in the interest of usefulness and simplicity. Any official name shall be the only official name used in any official compendium or for any other purpose of this Act. In no event shall the Secretary establish an official name so as to infringe a valid trademark.

(b) At such times as he may deem necessary, the Secretary shall review the official names by which drugs are identified in the official United States Pharmacopeia, the official Homeopathic Pharmacopeia of the United States, the official National Formulary, and all supplements thereto to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

(d) After each such review, the Secretary shall compile, publish, and distribute a list of all revised official names of drugs or devices designated under this section which list shall contain descriptive and explanatory matter the Secretary determines to be required for the effective use of those names.

* * *

REGISTRATION OF PRODUCERS OF DRUGS AND DEVICES

X SEC. 510.

(a) As used in this section --

(1) "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug or device package in the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user...

(b) On or before December 31 of each year every person who owns or operates any establishment engaged in the manufacture, preparation, propagation, compounding, or processing of drugs or devices shall register with the Secretary his name, places of business, and all such establishments.

(c) Every person -- upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates -- shall immediately register with the Secretary his name, place of business, and such establishment.

(d) Every person duly registered shall immediately register with the Secretary any additional establishment which he owns or operates and in which he begins manufacture, preparation, propagation, compounding, or processing of drugs or devices.

(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j) below.

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(f) The Secretary shall make available for inspection any registration filed pursuant to this section, except that any list or data submitted pursuant to subsection (j) below shall be exempt from inspection (unless such exemption would be inconsistent with protection of the public health).

(g) The foregoing subsections of this section shall not apply to --

- (1) pharmacies ...
- (2) practitioners licensed by law ...;
- (3) persons who manufacture ... drugs or devices solely for use in research, teaching or chemical analysis and not for sale;
- (4) such other classes of persons as the Secretary may by regulation exempt ...

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(h) Every establishment registered under this section shall be subject to inspection under section 704 [factory inspection] and every establishment dealing with drugs or devices classified in class II or III shall be inspected at least once in every two-year period.

(i) Any applicable establishment within any foreign country shall be required to provide the information required by subsection (j) below.

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(j) (1) Every person shall, at the time of registration file with the Secretary a list of all drugs and devices which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not filed with the Secretary before. Such list shall be prepared in such form and manner as the Secretary may prescribe and shall be accompanied by --

(A) in the case of a drug contained in the applicable list and subject to section 505 [new drugs] ... a reference to the authority for the marketing of such drug or device and a copy of all labeling for such drug or device;

(B) in the case of any other drug contained in an applicable list --

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(i) which is subject to section 503(b)(1) [dispensing prescription drugs], a copy of all labeling for such drug, a representative sampling of advertisements for such drug and, upon request made by the Secretary for good cause, a copy of all advertisements for a particular drug product, or

(ii) which drug is not subject to section 503(b)(1) [i.e., over the counter drug], the label and package insert for such drug or device and a representative sampling of any other labeling for such drug or device;

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(C) in the case of any prescription or non-prescription drug, a quantitative listing of its active ingredient or ingredients, except that -- with respect to a particular drug product -- the Secretary may require the submission of a quantitative listing of all ingredients if necessary to carry out the purposes of this Act ...

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(2) Each person who registers with the Secretary under this subsection shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following information:

(A) A list of each drug or device introduced by the registrant for commercial distribution which he has not previously filed with the Secretary. A list under this subparagraph shall list a drug or device by its established name (as defined in section 502(e)) and by any proprietary name it may have and shall be accompanied by the other information required by paragraph (1) above.

(B) If, since the date the registrant last made a report under this paragraph, he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug, notice of such discontinuance, the date of such discontinuance, and the identity of such drug or device.

(C) If, since a notice of discontinuance, the registrant has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a discontinued drug, notice of such resumption, the date of such resumption, the identity of the drug and the other information required by paragraph (1) above ...

(D) Any material change in information previously submitted pursuant to this paragraph or paragraph (1) above.

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(3) The Secretary may also require each registrant under this section to submit a list of each drug product which (A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and (B) contains a particular ingredient.

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NEW ANIMAL DRUGS

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SEC. 512.

(a) (1) A new animal drug shall be deemed unsafe for the purposes of section 501(a)(5) and section 402(a)(2)(D) unless --

(A) there is in effect an approved application filed pursuant to subsection (b) below with respect to its use or intended use,

(B) the drug, its labeling, and use conform to the approved application, and

(C) in the case of a new animal drug subject to subsection (n) below, it is from a batch for which a certificate is in effect...

(2) An animal feed bearing or containing a new animal drug shall be deemed unsafe for the purposes of section 501(a)(6) unless —

(A) there is in effect an approved application filed pursuant to subsection (b) below with respect to the drug, as used in the animal feed,

(B) there is in effect an approved application pursuant to subsection (m)(1) below with respect to such animal feed, and

(C) the animal feed, its labeling, and use conform to the conditions and indications of use published pursuant to subsection (i) below and to the application approved under subsection (m).

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 501(a)(5) or (6) if it is for investigational use and conforms to the terms of an exemption in effect under section 512(j).

(b) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug or in animal feed; (7) a description of practicable methods for

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determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (8) the proposed tolerance or withdrawal period or other use restrictions for such drug required in order to assure that the proposed use of such drug will be safe.

(c) Within one hundred and eighty days after the filing of an application pursuant to subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (1) issue an order approving the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or (2) give the applicant notice of an opportunity for a hearing.

(d) (1) If the Secretary finds, after notice and hearing, that --

(A) the investigations do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling;

(B) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

(E) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will be effective;

(F) upon the basis of the information submitted to him as part of the application or any other information before him with respect to such drug, the tolerance limitation proposed, if any, exceeds that reasonably required to accomplish the physical or other technical effect for which the drug is intended;

(G) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

(H) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (H) do not apply, he shall issue an order approving the application.

(2) In determining whether such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Secretary shall consider, among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice. Any order issued under this subsection refusing to approve an application shall state the findings upon which it is based.

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(3) As used in this subsection and subsection (e), "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

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(e) (1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of a new animal drug if he finds --

(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which application was approved;

(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (H) of paragraph (1) of subsection (d) applies to such drug;

(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

(D) that the application contains any untrue statement of a material fact; or

(E) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds --

(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records, or to make required reports in accordance with a regulation or order under subsection (1), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

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(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

XV

(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(3) Any order under this subsection shall state the findings upon which it is based.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d), (e), or (m) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate...

(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under subsection (b) or (m) of this section. The provisions of subsection (h) of section 505 of this Act shall govern any such appeal.

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(i) When a new animal drug application is approved, the Secretary shall publish in the Federal Register the name and address of the applicant and the conditions and indications of use covered by the application, including any tolerance withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed for use in which such drug is approved, and such other information upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval of such new animal drug application, or upon its suspension, the Secretary shall revoke or suspend, as the case may be, the regulation published pursuant to this subsection insofar as it is based on the approval of such application.

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XII (j) To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this section, new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. Such regulations may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable him to evaluate the safety and effectiveness of such article in the event of the filing of an application pursuant to this section...

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XII (1) (1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe... Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

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VIII (2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

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XV (m) (1) Any person may file with the Secretary an application with respect to any intended use or uses of an animal feed bearing or containing a new animal drug. The applicant shall submit (A) a full statement of the composition of such animal feed; (B) an identification of the regulation or regulations relating to the new animal drug or drugs to be used in such feed on which the application relies; (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed; (D) specimens of the labeling proposed to be used for such animal feed; and (E) if so requested by the Secretary, samples of such animal feed or its components.

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(2) Within ninety days after the filing of an application to subsection (m)(1), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if he then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing.

(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving him an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to him as part of the application or on the basis of any other information before him --

(A) that there is not in effect a regulation on the basis of which such application may be approved;

(B) that such animal feed (including the proposed use of any new animal drug therein or thereon) does not conform to an applicable regulation published pursuant to subsection (i) referred to in the application, or that the purposes and conditions or indications or use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable purposes and conditions or indications of use (including warnings) published pursuant to subsection (i) or such labeling omits or fails to conform to other applicable information published pursuant to subsection (i);

(C) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

XV

(D) that, based on a fair evaluation of all material facts, such labeling is false or misleading in any particular;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (D) do not apply, he shall issue an order approving the application.

(4) (A) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application with respect to any animal feed under this subsection if the Secretary finds --

(i) that the application contains any untrue statement of a material fact; or

(ii) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any animal feed under this subsection if the Secretary finds --

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(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5)(A) of this subsection, or the applicant has refused to permit access to, or copying or verification of, such records;

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(ii) that on the basis of new information before him, evaluated together with the evidence before him when such application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

XV

(iii) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such animal feed, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

(C) Any order under paragraph (4) of this subsection shall state the findings upon which it is based.

(5) In the case of any animal feed for which an approval of an application filed pursuant to this subsection is in effect --

XIII (A) the applicant shall establish and maintain such records, and reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b), as the Secretary may by general regulation, or by order with respect to such application, prescribe ...

VIII (B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

CHAPTER VI -- COSMETICS

ADULTERATED COSMETICS

XVI SEC. 601.

A cosmetic shall be deemed to be adulterated --

XV (a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use as are customary or usual; Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution -- This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye, and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

MISBRANDED COSMETICS

XV SEC. 602.

A cosmetic shall be deemed to be misbranded --

(a) If its labeling is false or misleading in any particular.

(b) If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

REGULATIONS MAKING EXEMPTIONS

XVII SEC. 603.

The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with

the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

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CHAPTER VII -- GENERAL

ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

XV SEC. 701.

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(a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801 [import and export drugs and devices] except as otherwise provided therein...

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401 [Definitions and Standards for Food], 403(j) [dietary food labels], 404(a) [Emergency Permit Control], 406 [Tolerances for Poisonous Ingredients in Food], 501(b) [drug quality control tests] or 502(d) [designation of habit-forming drugs], or 502(h) [drugs liable to deterioration labeling] shall begin by a proposal made by the Secretary or by petition of any interested persons...

EXAMINATIONS AND INVESTIGATIONS

II SEC. 702.

(a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department...

III (c) For purposes of enforcement of this Act, records of any department or independent establishment in the Executive Branch of the Government shall be open to inspection by any official of the Department of Health, Education, and Welfare duly authorized by the Secretary to make such inspection.

III (d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

VIII (e) Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this Act relating to counterfeit drugs may, when so authorized by the Secretary -- ...

(2) execute and serve search warrants...

* * *

RECORDS OF INTERSTATE SHIPMENT

SEC. 703.

VIII For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving or holding food, drugs, devices, or cosmetics in interstate commerce shall at reasonable times, upon the request of an officer designated by the Secretary, permit access to and copying of all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, and the quantity, shipper, and consignee thereof; and it shall be unlawful to fail to permit such access and copying ...

* * *

FACTORY INSPECTION

VIII SEC. 704.

(a) For purposes of enforcement of this Act, officers duly designated by the Secretary, upon presenting appropriate credentials and a written notice are authorized (1) to enter, at reasonable times, any

factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held or to enter any vehicle used to transport or hold such items; and (2) to inspect, in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities). No inspection shall extend to financial data, sales data other than shipment data, pricing data, personnel data and research data, other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to this Act...

PUBLICITY

XIV SEC. 705...

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

LISTING AND CERTIFICATION OF COLOR ADDITIVES
FOR FOODS, DRUGS, AND COSMETICS

WHEN COLOR ADDITIVES DEEMED UNSAFE

X SEC. 706.

(a) A color additive shall, with respect to any particular use (actual, intended or represented as suitable for, in, or on food or drugs or devices or cosmetics) be deemed unsafe (for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be) unless —

- (1) (A) the additive is listed in accordance with subsection (b) below and the additive and use conform with any provisions of that listing, and (B) the additive is from a certified batch if batch certification is required under subsection (c) below ...

LISTING OF COLORS

(b) (1) The Secretary shall, by regulation, provide for separately listing of color additives for use in or on food, drugs or devices, and cosmetics, if the additives are suitable and safe for such uses.

(2) (A) Any color additive may be listed for use generally in or on food, drugs or devices, or cosmetics...

(B) Any additive may be listed only for uses for which the available data established that is suitable and may safely be employed.

(3) Such regulations shall prescribe conditions under which the additive may be safely employed, including, but not limited to maximum quantities which may be used or permitted to remain in or on articles in or on which it is used; the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements.

(4) The Secretary shall not list a color additive unless the data before him establish that under the conditions specified, the additive will be safe: Provided, however, that a color additive shall be deemed to be suitable and safe for use generally in or on food if it is generally recognized by qualified experts as safe intended use, as provided in section 201(s).

II

(5) (A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider among other relevant factors --

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and

other impurities contained in such color additive, (II) such additive in or on any article of food, drug or devices, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of the additive, if it is found by the Secretary to induce cancer when ingested in appropriate tests...;

(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, any person who will be adversely affected by the proposal or by the Secretary's order may request that the petition or order be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) above;

(ii) Within sixty days (or ninety days if extended) the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the report shall be promptly supplied to any person who has filed a petition, or who has requested referral to the advisory committee. Within thirty days after that, the Secretary shall act upon the petition or other proposal...

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(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary --

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

CERTIFICATION OF COLORS

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) above and (2) for

exemption from the requirement of certification which he finds not to be necessary in the interest of the protection of the public health: Provided, that for GRAS substances batch certification shall be deemed not necessary.

* * *

REVISION OF UNITED STATES PHARMACOPEIA:
DEVELOPMENT OF ANALYSIS AND MECHANICAL
AND PHYSICAL TESTS

III [21 U.S.C. 377 -- Section 201 of the Labor-Federal Security
Appropriation Act, 1944]

The Secretary, in carrying into effect the provisions of this chapter, is authorized hereafter to cooperate with associations and scientific societies in the revision of the United States Pharmacopeia and in the development of methods and analyses and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration.

* * *

CONFIDENTIAL INFORMATION

XIV SEC. 708.

The Secretary may provide any information which is exempt from disclosure (pursuant to subsection (a) of section 552 of Title 5, United States Code, by reason of subsection (b)(4) of such section) to a person other than an officer or employee of the Department if he determines such other person requires the information in connection with an activity undertaken for the Secretary, in which the Secretary is not prohibited from using such information. The Secretary shall require that the person receiving the information take security precautions respecting the information the Secretary prescribes.

* * *

CHAPTER VIII -- IMPORTS AND EXPORTS

XVII SEC. 801.

(a) The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food,

drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony ... If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under unsanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, or misbranded then such article shall be refused admission...

(b) ... If it appears to the Secretary of Health, Education and Welfare that an article included within the provisions of clause (3) of subsection (a) above, by relabeling or other action can be brought into compliance with the Act, final determination as to admission of such article may be deferred ... the Secretary may authorize the applicant to perform such relabeling or other action...

(d) (1) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it --

(A) accords to the specifications of the foreign purchaser;

(B) is not in conflict with the laws of the country to which it is intended for export;

(C) is labeled on the outside of the shipping package that it is intended for export; and

(D) is not sold or offered for sale in domestic commerce.

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PUBLIC LAW 91-596 -- December 29, 1970

"OCCUPATIONAL SAFETY AND HEALTH ACT"**CONGRESSIONAL FINDINGS AND PURPOSE****SEC. 2...****XVII**

(b) The Congress declares it to be its purpose and policy to assure so far as possible every working man and woman in the Nation safe and healthful working conditions -- ...

(5) by providing for research in the field of occupational safety and health, including the psychological factors involved, and by developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems;

(6) by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety;

(7) by providing medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience;...

(9) by providing for the development and promulgation of occupational safety and health standards;...

(12) by providing for appropriate reporting procedures with respect to occupational safety and health that will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health problem;...

DEFINITIONS**SEC. 3.**

For the purposes of this Act:

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(1) "Secretary" means the Secretary of Labor...

- XVI (8) "Occupational safety and health standard" means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.
- XVI (9) "National consensus standard" means any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded the opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies.
- XVI (10) "Established Federal standard" means any operative occupational safety and health standard established by any agency of the United States and presently in effect, or contained in any Act of Congress in force on the date of enactment of this Act.
- XVI (11) "Committee" means the National Advisory Committee on Occupational Safety and Health established under this Act.
- XVI (12) "Director" means the Director of the National Institute for Occupational Safety and Health.
- XVI (13) "Institute" means the National Institute for Occupational Safety and Health established under this Act...

APPLICABILITY OF THIS ACT

SEC. 4...

- II (b) (3) The Secretary shall [before May 1974] report to Congress his recommendations for legislation to avoid unnecessary duplication and to achieve coordination between this Act and other Federal laws.

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OCCUPATIONAL SAFETY AND HEALTH STANDARDS

II SEC. 6...

- (b) The Secretary may by rule promulgate, modify, or revoke any occupational safety or health standard in the following manner:

IV (1) Whenever the Secretary, on the basis of information available to him, determines that a rule should be promulgated, he may request the recommendations of an advisory committee appointed under section 7 below. He shall provide the advisory committee with any proposals together with all pertinent information, including the results of research, demonstrations, and experiments. The advisory committee shall submit its recommendations...

(5) The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents, shall set the standard which most adequately assures, to the extent feasible, that no employee will suffer material impairment of health or functional capacity even if regularly exposed to the hazard for the period of his working life. Standards shall be based upon research, demonstrations, experiments, and other appropriate information. In addition to attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired...

XV (7) Any standard shall prescribe the use of labels or other appropriate forms of warning necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such standard shall also prescribe suitable protective equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees [see subsection 8(c)]. In addition, where appropriate, any such standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available to employees in order to most effectively determine whether their health is adversely affected by such exposure. In the event such medical examinations are in the nature of research, such examinations may be furnished at the expense of the Department of Health, Education, and Welfare. The results of such examinations or tests shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the employee, to his physician...

X (d) Any affected employer may apply to the Secretary for a variance from a standard. Affected employees shall be given notice of each such application and an opportunity to participate in a hearing. IV The Secretary shall grant a variance if he determines that the applicant has demonstrated, by a preponderance of the evidence, that the conditions, practices, means, methods, operations, or processes proposed to be used will provide safe and healthful employment. The variance shall prescribe the conditions the employer must maintain, and the practices, means, methods, operations, and processes which he must adopt and utilize...

ADVISORY COMMITTEES; ADMINISTRATION

IV SEC. 7.

(a) (1) There is hereby established a National Advisory Committee on Occupational Safety and Health consisting of twelve members composed of representatives of management, labor, occupational safety and occupational health professions, and of the public. The members shall be selected upon the basis of their experience and competence in the field of occupational safety and health.

(2) The Committee shall advise, consult with, and make recommendations to the Secretary and the Secretary of Health, Education, and Welfare on matters relating to the administration of the Act. The Committee shall hold no fewer than two meetings during each calendar year. All meetings of the Committee shall be opened to the public and a transcript shall be kept and made available for public inspection.

(b) An advisory committee may be appointed by the Secretary to assist him in his standard-setting functions under section 6 of this Act. Each such committee shall consist of not more than fifteen members and shall include representation for HEW, management, labor, and State health agencies.

(c) In carrying out his responsibilities under this Act, the Secretary is authorized to --

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(1) use, with the consent of any Federal agency, the services, facilities, and personnel of such agency, with or without reimbursement, and with the consent of any State or political subdivision thereof, accept and use the services, facilities, and personnel of any agency of such State or subdivision with reimbursement; and

(2) employ experts and consultants or organizations thereof as authorized by section 3109 of Title 5, United States Code.

INSPECTIONS, INVESTIGATIONS, AND RECORD-KEEPING

SEC. 8.

VIII

(a) In order to carry out the purposes of this Act, the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, is authorized --

(1) to enter without delay and at reasonable times any factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by an employee; and

(2) to inspect and investigate within reasonable limits and in a reasonable manner, any such place of employment and all pertinent conditions, structures, machines, apparatus, devices, equipment, and materials therein, and to question privately any such employer, owner, operator, agent or employee.

IX (b) In making his inspections and investigations under this Act the Secretary may require (by force of court order if necessary) the attendance and testimony of witnesses and the production of evidence under oath.

VII (c) (1) Each employer shall make, keep and preserve, and make
VIII available to the Secretary or the Secretary of Health, Education, and Welfare, such records regarding his activities relating to this Act as the Secretary, in cooperation with the Secretary of Health, Education, and Welfare, may prescribe by regulation as necessary for the effective enforcement of this Act for developing information regarding the causes and prevention of occupational accidents and illnesses. Such regulation may include provisions requiring periodic inspections. The Secretary shall also issue regulations requiring that employers, through posting of notices or other appropriate means, keep their employees informed of their protections and obligations under this Act, including the provisions of applicable standards.

VI (2) The Secretary, in cooperation with the Secretary of
XII Health, Education, and Welfare, shall prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses other than minor injuries...

III (3) The Secretary, in cooperation with the Secretary of
VI Health, Education, and Welfare, shall issue regulations requiring employers to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under section 6. Such regulations shall provide employees or their representatives an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Each employer shall promptly notify any employee who has been or is being exposed to toxic materials or harmful physical agents in concentrations or at levels which exceed those prescribed by an applicable occupational safety and health standard, and shall inform him of the corrective action being taken.

XVII (d) Any information obtained under this Act shall be obtained with a minimum burden upon employers, especially those operating small businesses. Unnecessary duplication of efforts in obtaining information shall be reduced to the maximum extent feasible...

VIII (f) (1) Any employee or representative of employees who believes that a violation of a standard exists or that an imminent danger exists, may request an inspection by the Secretary. Any request shall be reduced to writing, and shall set forth with reasonable particularity the grounds for the request. If the Secretary determines there are reasonable grounds he shall make a special inspection as soon as practicable, to determine if such violation or danger exists...

XIV (g) (1) The Secretary and the Secretary of Health, Education, and Welfare are authorized to compile, analyze, and publish, either in summary or detailed form, all reports or information obtained under this section.

VIII (2) The Secretary and the Secretary of Health, Education, and Welfare shall each prescribe such rules and regulations as he may deem necessary to carry out their responsibilities under this Act, including rules and regulations dealing with the inspection of an employer's establishment.

* * *

CONFIDENTIALITY OF TRADE SECRETS

XIV SEC. 15.

All information reported to or obtained by the Secretary in connection with any inspection or proceeding under this Act which contains or which might reveal a trade secret shall be considered confidential, except that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act. In any such proceeding the Secretary... or the court shall issue such orders as may be appropriate to protect the confidentiality of trade secrets.

* * *

STATE JURISDICTION AND STATE PLANS

XVII SEC. 18...

(c) The Secretary shall approve the plan submitted by a State if such plan in his judgment --...

VIII (3) provides for a right of entry and inspection of all workplaces subject to the Act which is at least as effective as that provided in section 8, and includes a prohibition on advance notice of inspections;...

XII (7) requires employers in the State to make reports to the Secretary in the same manner and to the same extent as if the plan were not in effect; and

XII (8) provides that the State agency will make such reports to the Secretary in such form and containing such information, as the Secretary shall from time to time require.

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RESEARCH AND RELATED ACTIVITIES

II SEC. 20.
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(a) (1) The Secretary of Health, Education, and Welfare, after consultation with appropriate Federal departments or agencies shall conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health, including studies of psychological factors involved, and relative to innovative methods, techniques, and approaches for dealing with occupational safety and health problems.

(2) The Secretary of Health, Education, and Welfare, shall consult with the Secretary in order to develop specific plans for such research, demonstrations, and experiments as are necessary to produce criteria, including criteria identifying toxic substances, enabling the Secretary to meet his responsibility for the formulation of safety and health standards under this Act; and the Secretary of Health, Education, and Welfare, on the basis of such research, demonstrations, and experiments and any other information available to him, shall develop and publish at least annually such criteria as will effectuate the purposes of this Act.

(3) The Secretary of Health, Education, and Welfare, on the basis of research, demonstrations, and experiments, and any other information available shall develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience.

(4) The Secretary of Health, Education, and Welfare shall also conduct special research, experiments, and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this Act...

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(5) The Secretary of Health, Education, and Welfare, in order to comply with his responsibilities under paragraph (2) above, and in order to develop needed information regarding potentially toxic substances or harmful physical agents, may prescribe regulations requiring employers to measure, record, and make reports on the exposure of employees to substances or physical agents which the Secretary of Health, Education, and Welfare reasonably believes may endanger the health or safety of employees. The Secretary of Health, Education, and Welfare also is authorized to establish such programs of medical examinations and tests as may be necessary for determining the incidence of occupational illnesses and the susceptibility of employees to such illnesses. Upon the request of any employer who is required to measure and record exposure of employees to substances or physical agents, the Secretary of Health, Education, and Welfare shall furnish full financial or other assistance to such employer for the purpose of defraying any additional expense incurred by him.

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(6) The Secretary of Health, Education, and Welfare shall publish, at least annually, a list of all known toxic substances by generic family or other useful grouping, and the concentrations at which such toxicity is known to occur. He shall determine, following a written request by any employer or authorized representative of employees, specifying with reasonable particularity the grounds on which the request is made, whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found; and shall submit such determination both to employers and affected employees as soon as possible. If the Secretary of Health, Education, and Welfare determines that any substance is potentially toxic at the concentrations in which it is used or found in a place of employment, and such substance is not covered by an occupational safety or health standard promulgated under section 6, the Secretary of Health, Education, and Welfare shall immediately submit such determination to the Secretary, together with all pertinent criteria.

(7) Annually, the Secretary of Health, Education, and Welfare shall conduct and publish industrywide studies of the effect of chronic or low-level exposure to industrial materials, processes, and stresses on the potential for illnesses, disease, or loss of functional capacity in aging adults.

VIII (b) The Secretary of Health, Education, and Welfare is authorized to make inspections and question employers and employees as provided in section 8 of this Act in order to carry out his functions and responsibilities under this section.

(c) The Secretary is authorized to enter into contracts, agreements or other arrangements with appropriate public agencies or private organizations for the purpose of conducting studies relating to his responsibilities under this Act. In carrying out his responsibilities under this subsection, the Secretary shall cooperate with the Secretary of Health, Education, and Welfare in order to avoid duplication of efforts.

XVII (e) The functions of the Secretary of Health, Education, and Welfare under this Act shall, to the extent feasible, be delegated to the Director of the National Institute for Occupational Safety and Health established by section 22 below.

* * *

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

IV SEC. 22.

II (a) It is the purpose of this section to establish a National Institute for Occupational Safety and Health in the Department of Health, Education, and Welfare in order to carry out the policy set forth in section 2 of this Act and to perform the functions of the Secretary of Health, Education, and Welfare under sections 20 and 21 of this Act...

(c) The Institute is authorized to --

(1) develop and establish recommended occupational safety and health standards...

(d) Upon his own initiative, or upon the request of the Secretary of Health, Education, and Welfare, the Director is authorized (1) to conduct such research and experimental programs as he determines are necessary for the development of criteria for new and improved occupational safety and health standards, and (2) after consideration of the results of such research and experimental programs make recommendations concerning new or improved occupational safety and health standards. Any occupational safety and health standard recommended pursuant to this section shall immediately be forwarded to the Secretary of Labor, and to the Secretary for Health, Education, and Welfare.

(e) In addition to any authority vested in the Institute by the other provisions of this section, the Director, in carrying out the functions of the Institute, is authorized to --...

(5) obtain the services of experts and consultants in accordance with the provisions of section 3109 of title 5, United States Code;...

* * *

STATISTICS

II SEC. 24.

III (a) In order to further the purposes of this Act, the Secretary, in consultation with the Secretary of Health, Education, and Welfare, shall develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics. Such program may cover all employments whether or not subject to any other provisions of this Act but shall not cover employments excluded by section 4. The Secretary shall compile accurate statistics on work injuries and illnesses which shall include all disabling, serious, or significant injuries and illnesses, whether or not involving loss of time from work, other than minor injuries...

(b) To carry out his duties under subsection (a) above, the Secretary may --

(1) promote, encourage, or directly engage in programs of studies, information and communication concerning occupational safety and health statistics;

(2) make grants to States in order to assist them in developing and administering programs dealing with occupational safety and health statistics; and

(3) arrange, through grants or contracts, for the conduct of such research and investigations which further the objectives of this section...

VII (e) On the basis of the records made and kept pursuant to section 8(c) of this Act, employers shall file such reports with the Secretary as he shall prescribe by regulation, as necessary to carry out his functions under this Act.

* * *

FMSHA-1

PUBLIC LAW 91-173 -- 1969

as amended by

PUBLIC LAW 95-164 -- November 9, 1977

FEDERAL MINE SAFETY AND HEALTH ACT of 1977

* * *

DEFINITIONS

SEC. 3.

For the purpose of this Act:

- XVI (a) "Secretary" means the Secretary of Labor or his delegate;...
- XVI (j) "Imminent danger" means the existence of any condition or practice in a coal or other mine which could reasonably be expected to cause death or serious physical harm before such condition or practice can be abated;
- XVI (k) "Accident" includes..., or injury to, or death of, any person;
- XVI (l) "Mandatory health or safety standard" means the interim mandatory health or safety standards established by Titles II and III of this Act, and the standards promulgated pursuant to Title I of this Act; ...
- XVI (n) "Administration" means the Mine Safety and Health Administration in the Department of Labor...

* * *

TITLE I -- GENERAL

MANDATORY SAFETY AND HEALTH STANDARDS

SEC. 101.

- II (a) The Secretary shall by rule develop, promulgate, and revise as appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in mines.

IV

(1) Whenever the Secretary determines that a rule should be promulgated in order to serve the objectives of this Act, he may request the recommendation of an advisory committee appointed under section 102(c) below. The Secretary shall provide such advisory committee with any proposals of his own or of the Secretary of Health, Education, and Welfare, together with all pertinent factual information available, including the results of research, demonstrations, and experiments. The advisory committee shall submit its recommendations regarding the rule to be promulgated within 60 days or within such longer or shorter period as may be prescribed by the Secretary, but in no event longer than 180 days...

IV

(3) ...Any hearing in connection with promulgating a mandatory safety or health standard for the purpose of hearing relevant information shall commence within 60 days. The Secretary may require by subpoena the attendance of witnesses and the production of evidence in connection with any proceeding initiated under this section...

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(6) (A) The Secretary, in promulgating mandatory standards dealing with toxic materials or harmful physical agents, shall set standards which most adequately assure (on the basis of the best available evidence) that no miner will suffer material impairment of health or functional capacity even if such miner has regular exposure to the hazards for the period of his working life. Development of mandatory standards shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the miner, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

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(B) The Secretary of Health, Education, and Welfare, as soon as possible, but no later than May 9, 1979, and on a continuing basis, shall, for each toxic material or harmful physical agent which is used or found in a mine, determine whether such material or agent is potentially toxic at the concentrations in which it is used or found in a mine. The Secretary of Health, Education, and Welfare shall submit such determinations to the Secretary. Thereafter, the Secretary of Health, Education, and Welfare shall submit to the Secretary all pertinent criteria regarding any such substances determined to be toxic or any such harmful agents as such criteria are developed...

- XV (7) Any mandatory health or safety standard promulgated under this subsection shall prescribe the use of labels or other appropriate forms of warning necessary to insure that miners are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure. Where appropriate, such mandatory standard shall also prescribe suitable protection equipment and control or technological procedures to be used in connection with such hazards and shall provide for monitoring or measuring miner exposure at such locations and intervals, and in such manner as to assure the maximum protection of miners. Where appropriate, any such mandatory standard shall prescribe the type and frequency of medical examinations or other tests which shall be made available to miners in order to most effectively determine whether the health of such miners is adversely affected by exposure. In the event such medical examinations are in the nature of research, such examinations may be furnished at the expense of the Secretary of Health, Education, and Welfare. The results of such examinations or tests made shall be furnished only to the Secretary or the Secretary of Health, Education, and Welfare, and, at the request of the miner, to his designated physician...
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ADVISORY COMMITTEES

SEC. 102...

- IV (c) The Secretary or the Secretary of Health, Education, and Welfare may appoint advisory committees as he deems appropriate to advise him in carrying out the provisions of this Act...

INSPECTIONS, INVESTIGATIONS, AND RECORD-KEEPING

SEC. 103.

- VIII (a) Authorized representatives of the Secretary or the Secretary of Health, Education, and Welfare shall make frequent inspections and investigations in coal or other mines each year for the purpose of (1) obtaining, utilizing, and disseminating information relating to health and safety conditions, the causes of accidents, and the causes of diseases and physical impairments originating in such mines, (2) gathering information with respect to mandatory health or safety standards, (3) determining whether an imminent danger exists, and (4) determining whether there is compliance with the mandatory health or safety standards or with any citation, order, or decision issued under this title or other requirements of this Act. In carrying out the requirements of this subsection, no advance notice of an inspection

shall be provided except that in carrying out the requirements of clauses (1) and (2) above, the Secretary of Health, Education, and Welfare may give advance notice. In carrying out the requirements of clauses (3) and (4) of this subsection, the Secretary shall make inspections of each underground coal or other mine in its entirety at least four times a year, and of each surface coal or other mine in its entirety at least two times a year.

- IV (b) For any investigation of any accident [see the definition of "accident" section 3(k)], the Secretary may hold public hearings, and
- IX may sign and issue subpoenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and administer oaths.
- VI (c) The Secretary, in cooperation with the Secretary of Health, Education, and Welfare, shall issue regulations requiring operators to maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under any applicable mandatory health or safety standard promulgated under this Act. Such regulations shall provide miners or
- XIV their representatives with an opportunity to observe such monitoring or measuring, and to have access to the records thereof. Such regulations
- XI shall also make appropriate provisions for each miner or former miner to have access to records that indicate his own exposure to toxic materials. Each operator shall promptly notify any miner who has been or is being exposed to toxic materials in concentrations which exceed those prescribed by an applicable mandatory health or safety standard, and shall inform any miner who is being thus exposed of the corrective action being taken.
- VI (d) All accidents shall be investigated by the operator or his agent to determine the cause and the means of preventing a recurrence. Records of such accidents and investigations shall be kept and the
- XIV information shall be made available to the Secretary or his authorized representative and the appropriate State agency. Such records shall be open for inspection by interested persons. Such records shall include
- XII man-hours worked and shall be reported at a frequency determined by the Secretary but at least annually.
- XVII (e) Any information obtained by the Secretary or by the Secretary of Health, Education, and Welfare under this Act shall be obtained in such a manner as not to impose an unreasonable burden upon operators, especially those operating small businesses, consistent with the underlying purposes of this Act. Unnecessary duplication of effort in obtaining information shall be reduced to the maximum extent feasible...
- VIII (g) (1) Whenever a miner or his representative has grounds to believe that a violation of this Act or a mandatory health or safety standard exists, or an imminent danger exists, such miner or representative shall have a right to obtain an immediate inspection by giving notice to the Secretary of such violation or danger...

VIII (h) In addition to records specifically required by this Act, every operator of a mine shall establish and maintain such records, make such reports, and provide such information, as the Secretary or the Secretary of Health, Education, and Welfare may reasonably require to enable him to perform his functions under this Act. The Secretary or the XIV Secretary of Health, Education, and Welfare is authorized to compile, analyze, and publish, either in summary or detailed form, such reports of information. Except to the extent otherwise specifically provided by this Act, all records, information, reports, findings, citations, notices, orders, or decisions required to be issued under this Act may be published, may be released to any interested person, and shall be made available for public inspection.

VIII (i) Whenever the Secretary finds...that there exists in a mine some especially hazardous condition he shall provide a minimum of one spot inspection by his authorized representative of all or part of such mine during every five working days at irregular intervals...

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POSTING OF ORDERS AND DECISIONS

SEC. 109.

XV (a) At each mine there shall be maintained an office with a conspicuous sign designating it as the office. There shall be a bulletin board at such office or located at a conspicuous place near an entrance of such mine, so that orders, citations, notices, and decisions required by law or regulation to be posted, may be posted thereon, and be easily visible to all persons desiring to read them, and be protected against damage by weather and against unauthorized removal. A copy of any order, citation, notice or decision required by this Act to be given to an operator shall be delivered to the office of the affected mine, and a copy shall be immediately posted on the bulletin board...

X (d) Each operator of a coal or other mine subject to this Act shall file with the Secretary the name and address of the mine and the name and address of the person who controls or operates the mine. Each operator of a mine subject to this Act shall designate a responsible official as the principal officer in charge of health and safety at that mine.

* * *

TITLE II -- INTERIM MANDATORY HEALTH STANDARDS

COVERAGE

XVII SEC. 201.

(a) The provisions of sections 202 through 206 of this title and the applicable provisions of section 318 of Title III shall be

interim mandatory health standards applicable to all underground coal mines until superseded in whole or in part by improved mandatory health standards promulgated by the Secretary under the provisions of section 101 of this Act, and shall be enforced in the same manner and to the same extent as any mandatory health standard promulgated under the provisions of section 101 of this Act.

(b) Among other things, it is the purpose of this title to provide, to the greatest extent possible, that the working conditions in each underground coal mine are sufficiently free of respirable dust concentrations in the mine atmosphere to permit each miner the opportunity to work underground during the period of his entire working life without incurring any disability of pneumoconiosis or any other occupation-related disease during or at the end of such period.

DUST STANDARD AND RESPIRATORY EQUIPMENT

SEC. 202.

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(a) Each operator of a coal mine shall take accurate samples of the amount of respirable dust in the mine atmosphere by any device approved by the Secretary and in accordance with such methods, at such locations, at such intervals, and in such manner as the Secretary shall prescribe. The samples shall be transmitted to the Secretary for analysis and recording... The results of such samples shall also be made available to the operator who shall also report as to the conditions in the active workings of the mine, including, but not limited to, the average number of working hours during each shift, and quantity and velocity of air regularly reaching the working faces, the method of mining, the amount and pressure of the water, if any, reaching the working faces, and the number, location, and type of sprays, if any, used.

(b) Except as otherwise provided in this subsection ---

(1) Effective November 9, 1980, or the operative date of this title, each operator shall continuously maintain the average concentration of respirable dust at or below 3.0 milligrams per cubic meter of air.

(2) Effective November 9, 1983, the average concentration of respirable dust in the mine shall be maintained at or below 2.0 milligrams per cubic meter of air.

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(3) Any operator who determines that he will be unable, using available technology, to comply with the provisions of (b)(1) or (b)(2) above may file an application for a permit for noncompliance. A permit will be issued only if the application satisfies the requirements of subsection (c) below.

(4) [An application, or permit may be renewed]...

X (c) Any application for an initial or renewal permit shall contain --

(1) a representation by the applicant and the engineer conducting the survey referred to in paragraph (2) below that the applicant is unable to comply with the standard at specified working places because technology for reducing the concentration of respirable dust at such places is not available...

(2) an identification of the working places for which the permit is requested; the results of an engineering survey of the respirable dust conditions of each working place with respect to which such application is filed and the ability to reduce such dust to the level required to be maintained under this section; a description of the ventilation system of the mine and its capacity; the quantity and velocity of air regularly reaching the working faces; the method of mining; the amount and pressures of the water, if any, reaching the working faces; the number, location, and type of sprays, if any; action taken to reduce such dust; and such other information as may be required; and

(3) statements, by the applicant and the engineer conducting such survey, of the means and methods to be employed to achieve compliance with the applicable standard, the progress made toward achieving compliance, and an estimate of when compliance can be achieved...

VIII (g) The Secretary shall cause to be made such frequent spot inspections of the active workings of coal mines as he deems appropriate for the compliance with the provisions of this title.

MEDICAL EXAMINATIONS

SEC. 203.

V (a) The operator of a coal mine shall cooperate with the Secretary of Health, Education, and Welfare in making available to each miner working in a coal mine the opportunity to have a chest [x-ray] at given intervals to detect development of pneumoconiosis...

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TITLE III -- INTERIM MANDATORY SAFETY
STANDARDS FOR UNDERGROUND COAL MINES

* * *

VENTILATION

SEC. 303.

- VI (a) All coal mines shall be ventilated by mechanical ventilation equipment installed and operated in a manner approved by an authorized representative of the Secretary and such equipment shall be examined daily and a record shall be kept of such examination...
- VIII (d) (1) Within three hours preceding the beginning of any shift, and before any miner enters the active workings of a coal mine, certified persons designated by the operator of the mine shall examine such workings. Each examiner shall examine for hazards and violations of the mandatory health or safety standards. If such mine examiner finds a dangerous condition he shall post a "DANGER" sign and notify the operator of the mine. Each such mine
- XV examiner shall record the results of his examination with ink or indelible pencil in a book approved by the Secretary kept for such purpose...
- VIII (e) At least once during each coal-producing shift, or more often if necessary for safety, each working section shall be examined for hazardous conditions by certified persons designated by the operator to do so. Any such condition shall be corrected immediately...

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MAPS

SEC. 312.

- VI (a) The operator of a coal mine shall have in a fire-proof repository located at the surface of the mine a detailed accurate and up-to-date map of such mine drawn on scale. Such map shall be revised and supplemented at intervals prescribed by such engineer or surveyor.
- XIV (b) The map shall be available for inspection by the Secretary, coal mine examiners, miners and their representatives and persons owning land or residing on the surface above the mines. Such map or revision and supplement shall be kept confidential and its contents not divulged to any other person, except to the extent necessary to carry out the provisions of this Act and in connection with the functions and responsibilities of the Secretary of Housing and Urban Development.

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TITLE V -- ADMINISTRATION

RESEARCH

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SEC. 501.

(a) The Secretary of the Interior and the Secretary of Health, Education, and Welfare shall conduct such studies, research, experiments, and demonstrations as may be appropriate --

(1) to improve working conditions and practices in coal or other mines, and to prevent accidents and occupational diseases originating in the coal or other mining industry;...

(4) to develop new or improved means and methods of reducing concentrations of respirable dust in the mine atmosphere;

(5) to develop epidemiological information to (A) identify and define positive factors involved in occupational diseases of miners, (B) provide information on the incidence and prevalence of pneumoconiosis and other respiratory ailments of miners, and (C) improve mandatory health standards;

(6) to develop techniques for the prevention and control of occupational diseases of miners, including tests for hypersusceptibility and early detection;

(7) to evaluate the effect on bodily impairment and occupational disability of miners afflicted with an occupational disease;

(8) to prepare and publish from time to time reports on all significant aspects of occupational diseases of miners as well as on the medical aspects of injuries, other than diseases, which are revealed by the research carried on pursuant to this subsection;

(9) to study the relationship between coal or other mine environments and occupational diseases of miners;...

(11) to determine, upon written request by any operator or representative of miners whether any substance normally found in a coal or other mine has potentially toxic effects in the concentrations normally found in the mine or whether any physical agents or equipment found or used in a coal or other mine has potentially hazardous effects, and shall submit such determinations to both the operators and miners as soon as possible; and

(12) for such other purposes as they deem necessary to carry out the purposes of this Act...

(d) The Secretary of Health, Education, and Welfare shall also conduct studies and research into matters involving the protection of life and the prevention of diseases in connection with persons, who although not miners, work with, or around the products of coal or other mines in areas outside of such mines and under conditions which may adversely affect the health and well-being of such persons.

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PUBLIC LAW 92-573 -- October 27, 1972

as amended by

PUBLIC LAW 94-284 -- May 11, 1976

"CONSUMER PRODUCT SAFETY ACT"

* * *

DEFINITIONS

SEC. 3.

(a) For purposes of this Act:

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(1) "Consumer product" means any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; but such term does not include -- [tobacco, automobiles, pesticides, aircraft, boats, food, drugs or cosmetics].

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(2) "Consumer product safety rule" means a consumer product safety standard described in section 7(a), or a rule under this Act declaring a consumer product a banned hazardous product.

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(3) "Risk of injury" means a risk of death, personal injury, or serious or frequent illness...

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(7) (A) "Private labeler" means an owner of a brand or trademark on the label of a consumer product which bears a private label.

(B) A consumer product bears a private label if (i) the product is labeled with the brand or trademark of a person other than a manufacturer of the product, (ii) the person with whose brand or trademark the product is labeled has authorized or caused the product to be so labeled, and (iii) the brand or trademark of a manufacturer of such product does not appear on such label.

* * *

PRODUCT SAFETY INFORMATION AND RESEARCH

II SEC. 5.

(a) The Commission shall --

(1) maintain an Injury Information Clearinghouse to collect, investigate, analyze, and disseminate injury data, and information, relating to the causes and prevention of death, injury, and illness associated with consumer products; and

(2) conduct such continuing studies and investigations of deaths, injuries, diseases, other health impairments, and economic losses resulting from accidents involving consumer products as it deems necessary.

(b) The Commission may --

(1) conduct research, studies, and investigations on the safety of consumer products and on improving the safety of such products;

(2) test consumer products and develop product safety test methods and testing devices; and

(3) ...assist public and private organizations, administratively and technically, in the development of safety standards and test methods...

PUBLIC DISCLOSURE OF INFORMATION

XIV SEC. 6.

(a) (1) Nothing contained in this Act shall be deemed to require the release of any information described by subsection (b) of section 552, title 5, United States Code, or which is otherwise protected by law from disclosure to the public.

(2) All information reported to or obtained by the Commission under this Act which contains or relates to a trade secret shall be considered confidential and shall not be disclosed, except that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act.

(b) (1) Except as provided by paragraph (2) below, not less than 30 days prior to public disclosure of any information (unless the Commission finds that the public health and safety require a lesser period of notice), the Commission shall, to the extent practicable, notify, and provide a summary of the information to, each manufacturer or private labeler of any consumer product to which such information pertains, if the information will permit the public to readily ascertain the identity of such manufacturer or private labeler, and shall provide such manufacturer or private labeler with a reasonable opportunity to submit comments... If the Commission finds that it has made public disclosure of inaccurate or misleading information which reflects adversely upon the safety of any consumer product or the practices of any manufacturer, private labeler, distributor, or retailer of consumer products, it shall, in a manner similar to that in which such disclosure was made, publish a retraction of such inaccurate or misleading information.

(2) Paragraph (1) (except for the last sentence) shall not apply to the public disclosure of (A) information about any consumer product with respect to which the Commission has filed an action under section 12 (relating to imminently hazardous products), or which the Commission has reasonable cause to believe is in violation of section 19 (relating to prohibited acts), or (B) information in the course of or concerning any administrative or judicial proceeding under this Act.

(c) The Commission shall communicate to each manufacturer of a consumer product, insofar as may be practicable, information as to any significant risk of injury associated with such product.

CONSUMER PRODUCT SAFETY STANDARDS

II SEC. 7.

(a) (1) The Commission may by rule promulgate consumer product safety standards. A consumer product safety standard shall consist of one or more of the following of requirements:

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(A) Requirements as to packaging of a consumer product.

(B) Requirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions.

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(2) No consumer product safety standard shall require, incorporate, or reference any sampling plan. (The preceding sentence shall not apply to a fabric, related material, or product which is subject to a flammability standard under the Flammable Fabrics Act, or to glass containers.)

(b) A proceeding for the development of a consumer product safety standard shall be commenced by publication in the Federal Register of a notice which shall --

(1) identify the product and the nature of the risk of injury associated with the product;...

(3) include information with respect to any existing standard known to the Commission which may be relevant to the proceeding; and

(4) include an invitation for any person to submit within 30 days (A) an existing standard as the proposed consumer product safety standard or (B) to offer to develop a proposed consumer product safety standard.

(c) If the Commission determines that (1) there exists a standard which has been issued or adopted by any Federal agency or by any other qualified agency, organization, or institution, and (2) such standard if promulgated under this Act, would eliminate or reduce the unreasonable risk of injury associated with the product, then it may, in lieu of accepting an offer pursuant to subsection (d) of this section, publish such standard as a proposed consumer product safety rule.

(d) (1) Except as provided by subsection (c) above, the Commission shall accept one, and may accept more than one, offer to develop a proposed consumer product safety standard if it determines that the offeror is technically competent, is likely to develop an appropriate standard within the period specified in the invitation and will comply with the regulations of the Commission under paragraph (3) below...

(3) The Commission shall prescribe regulations governing the development of consumer product safety standards... Such regulations shall include requirements --

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(A) that standards recommended for promulgation be supported by test data or such other documents or materials as the Commission may reasonably require to be developed, and (where appropriate) contain suitable test methods for measurement of compliance with such standards...

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(C) for the maintenance of records, which shall be available to the public, to disclose the course of the development of standards, the comments and other information submitted by any person in connection with such development and such other matters as may be relevant to the evaluation of such recommended standards; and

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(D) that the Commission and the Comptroller General of the United States, or any of their duly authorized representatives, have access for the purpose of audit and examination to any books, documents, papers, and records relevant to the development of such recommended standards...

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ADMINISTRATIVE PROCEDURE APPLICABLE TO PROMULGATION
OF CONSUMER PRODUCT SAFETY RULES

SEC. 9...

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(b) In promulgating a consumer product safety rule the Commission shall consider relevant available product data including the results of research, development, testing, and investigation activities conducted generally and pursuant to this Act.

II

(c) (1) Prior to promulgating a consumer product safety rule, the Commission shall consider, and shall make appropriate findings for inclusion in such rule with respect to --

(A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce;

(B) the approximate number of consumer products, or types or classes thereof, subject to such rule;

(C) the public need for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products; and

(D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety...

COMMISSION RESPONSIBILITY -- PETITION FOR
CONSUMER PRODUCT SAFETY RULE

X SEC. 10.

(a) Any interested person may petition the Commission to commence a proceeding for the issuance, amendment or revocation of a consumer product safety rule.

IV (b) Such petition shall... set forth its factual basis and briefly describe the desired action.

(c) The Commission may hold a public hearing or conduct such investigation or proceeding as it deems appropriate in regards to such petition...

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IMMINENT HAZARDS

SEC. 12.

XVII (a) The Commission may file in a United States district court an action (1) against an imminently hazardous consumer product for seizure of such product, or (2) against any person who is a manufacturer, distributor, or retailer of such product, or (3) against both. Such an action may be filed notwithstanding the existence of a consumer product safety rule applicable to such product, or any pending administrative or judicial proceedings under any other provision of this Act. As used in
XVI this section, and hereinafter in this Act, "imminently hazardous consumer product" means a consumer product which presents imminent and unreasonable risk of death, serious illness, or severe personal injury...

IV (d) (1) Prior to commencing an action under subsection (a) above, the Commission may consult the Product Safety Advisory Council (established under section 28) with respect to its determination to commence such action, and request the Council's recommendations as to the type of temporary or permanent relief which may be necessary to protect the public.

(2) The Council shall submit its recommendations to the Commission within one week of such request.

IV (3) Subject to paragraph (2), the Council may conduct such hearing or offer such opportunity for the presentation of views as it may consider necessary or appropriate...

NEW PRODUCTS

SEC. 13.

- XI (a) The Commission may, by rule, prescribe procedures for the purpose of ensuring that the manufacturer of any new consumer product furnish notice and a description of such product to the Commission before its distribution in commerce.
- XVI (b) For purposes of this section, the term "new consumer product" means a consumer product which incorporates a design, material, or form of energy exchange which (1) has not previously been used substantially in consumer products and (2) for which there exists a lack of information adequate to determine the safety of such product in use by consumers.

PRODUCT CERTIFICATION AND LABELING

SEC. 14.

- XI (a) (1) Every manufacturer of a product which is subject to a consumer product safety standard and which is distributed in commerce (and the private labeler of such product if it bears a private label) shall issue a certificate certifying that such product conforms to all applicable consumer product safety standards, and specifying any applicable standard. Such certificate shall accompany the product or shall otherwise be furnished to any distributor or retailer to whom the product is delivered. Any certificate under this subsection shall be based on a test of each product or upon a reasonable testing program; shall state the name of the manufacturer or private labeler issuing the certificate; and shall include the date and place of manufacture...
- (b) The Commission may by rule prescribe reasonable testing programs for consumer products which are subject to consumer product safety standards under this Act and for which a certificate is required under subsection (a).
- XV (c) The Commission may by rule require the use and prescribe the form and content of labels which contain any or all of the following information:
- (1) The date and place of manufacture of any consumer product.
- (2) A suitable identification of the manufacturer of the consumer product, unless the product bears a private label in which case it shall identify the private labeler and shall also contain a code mark which will permit the seller of such product to identify the manufacturer to the purchaser upon request.

XI

(3) In the case of a consumer product subject to a consumer product safety rule, a certification that the product meets all applicable consumer product safety standards and a specification of the standards which are applicable.

Such labels, where practicable, may be required by the Commission to be permanently marked on or affixed to any such consumer product...

NOTIFICATION AND REPAIR, REPLACEMENT, OR REFUND

SEC. 15.

XVI

(a) For purposes of this section: "Substantial product hazard" means -- ...

(1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public.

(2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public:

XI

(b) Every manufacturer, distributor and retailer of a consumer product who obtains information which reasonably supports the conclusion that such product --

(1) fails to comply with an applicable consumer product safety rule, or

(2) contains a defect which could create a substantial product hazard,

shall immediately inform the Commission of such failure to comply or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

XI

(c) If the Commission determines (after affording an opportunity for a hearing) that a product presents a substantial hazard and that notification is required in order to adequately protect the public from such substantial hazard, the Commission may order the manufacturer or any distributor or retailer of the product to take any one or more of the following actions:

(1) To give public notice of the defect or failure to comply.

(2) To mail notice to each person who is a manufacturer, distributor, or retailer of such product.

(3) To mail notice to every person to whom the person required to give notice knows such product was delivered or sold.

Any such order shall specify the form and content of any notice required to be given under such order...

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INSPECTION AND RECORD-KEEPING

SEC. 16.

VIII (a) For purposes of implementing this Act, or rules or orders prescribed under this Act, officers of the Commission, upon presenting appropriate credentials and a written notice from the Commission to the owner, operator, or agent in charge, are authorized --

(1) to enter, at reasonable times, (A) any factory, warehouse, or establishment in which consumer products are manufactured or held, in connection with distribution in commerce, or (B) any conveyance being used to transport consumer products in connection with distribution in commerce; and

(2) to inspect, at reasonable times and in a reasonable manner such conveyance or those areas of such factory, warehouse, or establishment where such products are manufactured, held, or transported and which may relate to the safety of such products.

VII (b) Every person who is a manufacturer, private labeler, or distributor of a consumer product shall establish and maintain such records, make such reports, and provide such information as the Commission may, by rule, reasonably require for the purposes of implementing this Act, or to determine compliance with rules or orders prescribed under this Act. Upon request of an officer of the Commission, VIII every such manufacturer, private labeler, or distributor shall permit the inspection of appropriate books, records, and papers relevant to determining whether such manufacturer, private labeler, or distributor has acted or is acting in compliance with this Act and rules under this Act.

IMPORTED PRODUCTS

XVII SEC. 17.

(a) Any consumer product offered for importation into the customs territory of the United States shall be refused admission if such product --

(1) fails to comply with an applicable consumer product safety rule;

(2) is not accompanied by a certificate required by section 14, or is not labeled in accordance with regulations under section 14(c);

(3) is or has been determined to be an imminently hazardous consumer product in a proceeding brought under section 12;

(4) has a product defect which constitutes a substantial product hazard (within the meaning of section 15(a)(2)); or

(5) is a product which was manufactured by a person who the Commission has informed the Secretary of the Treasury is in violation of subsection (g) below.

(b) The Secretary of the Treasury shall obtain without charge and deliver to the Commission upon request, a reasonable number of samples of consumer products being offered for import...

(g) The Commission may, by rule, condition the importation of a consumer product on the manufacturer's compliance with the inspection and record-keeping requirements of this Act and the Commission's rules with respect to such requirements.

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PROHIBITED ACTS

XVII SEC. 19.

(a) It shall be unlawful for any person to --

(1) manufacture for sale, offer for sale, distribute in commerce, or import into the United States any consumer product which is not in conformity with an applicable consumer product safety standard under this Act;...

(2) manufacture for sale, offer for sale, distribute in commerce, or import into the United States any consumer product which has been declared a banned hazardous product by a rule under this Act;

(3) fail or refuse to permit access to or copying of records, or fail or refuse to establish or maintain records, or fail or refuse to make reports or provide information, or fail or refuse to permit entry or inspection, as required under this Act or rule thereunder;

(4) fail to furnish information required by section 15(b) [informing the Commission of substantial product hazards];

(5) fail to comply with an order issued under section 15(c) [informing the public of substantial product hazards];

(6) fail to furnish a certificate required by section 14 or issue a false certificate...; or to fail to comply with any rule under section 14(c) (relating to labeling);...

(8) fail to comply with any rule under section 13 (relating to prior notice and description of new consumer products); or

(9) fail to comply with any rule under section 27(e) (relating to provision of performance and technical data)...

* * *

EFFECT ON PRIVATE REMEDIES

SEC. 25...

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(c) Subject to sections 6(a)(2) and 6(b) but notwithstanding section 6(a)(1), any accident or investigation report made under this Act shall be available to the public... and all reports on research projects, demonstration projects, and other related activities shall be public information.

* * *

ADDITIONAL FUNCTIONS OF COMMISSION

SEC. 27.

IV

(a) The Commission may, conduct any hearing or other inquiry necessary or appropriate to its functions. The Commission shall publish notice of any proposed hearing and afford a reasonable opportunity for interested persons to present relevant testimony and data.

(b) The Commission shall also have the power --

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(1) to require, by special or general orders, any person to submit in writing such reports and answers to questions as the Commission may prescribe; and such submission shall be made within such reasonable period and under oath or otherwise as the Commission may determine;

- (2) to administer oaths;
- IX (3) to require by subpoena the attendance and testimony of witnesses and the production of all documentary evidence relating to the execution of its duties;
- (4) in any proceeding or investigation to order testimony to be taken by deposition before any person who is designated by the Commission and has the power to administer oaths and, in such instances, to compel testimony and the production of evidence in the same manner as authorized under paragraph (3) above;...
- XII (e) The Commission may by rule require any manufacturer of consumer products to provide to the Commission such performance and technical data related to performance and safety as may be required to carry out the purposes of this Act, and to give such notification of
- XI such performance and technical data at the time of original purchase to prospective purchasers and to the first purchaser of such product for purposes other than resale.
- (f) For purposes of carrying out this Act, the Commission may require any manufacturer, distributor, or retailer to sell a product to the Commission at cost...
- II (h) The Commission may plan, construct, and operate a facility or facilities suitable for research, development, and testing of consumer products in order to carry out this Act...
- II (j) The Commission shall prepare and submit to the President and the Congress at the beginning of each regular session of Congress a comprehensive report on the administration of this Act for the preceding fiscal year. Such report shall include --
 - (1) a thorough appraisal, including statistical analyses, estimates, and long-term projections of the incidence of injury and effects to the population resulting from consumer products, with a breakdown, insofar as practicable, among the various sources of such injury;...
 - (5) an analysis and evaluation of public and private consumer product safety research activities;...

PRODUCT SAFETY ADVISORY COUNCIL

IV SEC. 28.

- (a) The Commission shall establish a Product Safety Advisory Council which it may consult before taking any action under this Act. The Council shall be appointed by the Commission and shall be composed of fifteen qualified members, as follows:

(1) five members shall be selected from governmental agencies including Federal, State, and local governments;

(2) five members shall be selected from consumer product industries including at least one representative of small business; and

(3) five members shall be selected from among consumer organizations, community organizations, and recognized consumer leaders.

(b) The Council shall meet at the call of the Commission, but not less often than four times during each calendar year.

XIV

(c) The Council may propose consumer product safety rules to the Commission for its consideration and may function through subcommittees of its members. All proceedings of the Council shall be public, and a record of each proceeding shall be available for public inspection...

COOPERATION WITH STATES AND WITH OTHER FEDERAL AGENCIES

III

SEC. 29...

(c) The Commission may obtain from any Federal department or agency such statistics, data, program reports, and other materials necessary to carry out its functions under this Act. Each such department or agency may cooperate with the Commission and, to the extent permitted by law, furnish such materials to it. The Commission and the heads of other departments and agencies engaged in administering programs related to product safety shall, to the maximum extent practicable, cooperate and consult in order to insure fully coordinated efforts.

(d) The Commission shall, to the maximum extent practicable, utilize the resources and facilities of the National Bureau of Standards, on a reimbursable basis, to perform research and analyses related to risks of injury associated with consumer products (including fire and flammability risks), to develop test methods, to conduct studies and investigations, and to provide technical advice and assistance in connection with the functions of the Commission.

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[Note: The responsibilities of the Secretary of Health, Education and Welfare under this Act were transferred to the Consumer Product Safety Commission by P.L. 92-573. For clarity the term "Commission" has been substituted for "Secretary" as appropriate.]

"FEDERAL HAZARDOUS SUBSTANCES ACT"

As amended by PUBLIC LAW 89-756; PUBLIC LAW 91-113;
PUBLIC LAW 91-452 and PUBLIC LAW 94-284]

* * *

DEFINITIONS

SEC.2.

For the purposes of this Act:...

XVI (d) "Commission" means the Consumer Product Safety Commission...

XVI (f) "Hazardous substance" means:

(1) (A) Any substance or mixture which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture may cause substantial personal injury or substantial illness as a result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.

(B) Any substances which the Commission (by regulation) finds meet the requirements of subparagraph (1)(A) above.
(See subsection 3(a))

(C) Any radioactive substance, which (as used in a particular class of article or as packaged) the Commission determines is sufficiently hazardous to require labeling in order to protect the public health.

(2) "Hazardous substance" shall not apply to pesticides, foods, drugs, cosmetics, fuels or tobacco and tobacco products, but such term shall apply to any article which is not itself a pesticide but which is a hazardous substance by reason of bearing or containing such economic poison.

(3) "Hazardous substance" shall not include any source material, special nuclear material, or byproduct material.

XVI (g) "Toxic" shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface.

XVI (h) (1) "Highly toxic" means any substance which falls within any of the following categories: (a) produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered,... or when inhaled continuously for a period of one hour or less at an atmospheric concentration of two hundred parts per million by volume or less of gas or vapor or two milligrams per liter or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner;... or (c) produces death within fourteen days in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for twenty-four hours or less.

(2) If the Commission finds that available data on human experience with any substance indicates results different from those obtained on animals in the above-named dosages or concentrations, the human data shall take precedence.

XVI (i) "Corrosive" means any substance which, in contact with living tissue, will cause destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces.

XVI (j) "Irritant" means any substance not corrosive within the above meaning which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

XVI (k) "Strong sensitizer" means a substance which will cause, through an allergic or photodynamic process, a hypersensitivity of normal living tissue which becomes evident on reapplication of the same substance. Before designating any substance as a strong sensitizer, the Commission, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has significant potential for causing hypersensitivity...

XVI (p) "Misbranded hazardous substance" means a hazardous substance
XV intended for use in the household or by children, if the packaging or labeling of the substance is in violation of an applicable regulation issued under section 3 or 4 of the Poison Prevention Packaging Act of 1970 or if the substance, unless exempted by section 3 below, fails to bear a label--

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common, usual or chemical name of each component which contributes substantially to its hazard, (unless the Commission by regulation permits or requires the use of a recognized generic name); (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as "Flammable", "Combustible", "Vapor Harmful", "Causes Burns", "Absorbed Through Skin", or similar wording; (F) precautionary measures describing the action to be followed or avoided; (G) instruction, when appropriate, for first-aid treatment; (H) the word "poison" for any "high toxic" substance; (I) instructions on packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

(2) on which any required statements are located prominently in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

XVI

(q) (1) "Banned hazardous substance" means (A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner that a child might be exposed to the substance; or (B) any hazardous substance intended for use in the household which the Commission by regulation classifies as a "banned hazardous substance" on finding that the degree or nature of the hazard involved in its presence or use in households is such that protection of the public health and safety can be adequately served only by keeping such substance out of interstate commerce (any existing or possible labeling requirement notwithstanding): Provided, that the Commission by regulation (i) shall exempt articles, such as chemical sets, which require inclusion of a hazardous substance(s),... and (ii) shall exempt from clause (A), and provide for the labeling of, common fireworks to the extent that it determines such articles can be adequately labeled to protect purchasers and users...

REGULATIONS DECLARING HAZARDOUS SUBSTANCES AND ESTABLISHING VARIATIONS AND EXEMPTIONS

SEC. 3.

XVI

(a) (1) Whenever the Commission finds that the objectives of this Act will be promoted (by avoiding or resolving uncertainty

as to its application), it may by regulation declare any substance or mixture (which it finds meets the requirements stated above) to be a hazardous substance for the purposes of this Act...

XV (b) If the Commission finds that labeling requirements under section 2(p)(1) are not adequate for protection of the public health and safety in view of the special hazard presented by any particular hazardous substance, it may by regulation establish reasonable variations or additional label requirements as necessary...

XV (c) If the Commission finds that full compliance with labeling requirements otherwise applicable under this Act are impracticable or not necessary for adequate protection of the public health and safety, it shall promulgate regulations exempting any such substance from these requirements to an appropriate extent.

X (d) The Commission may exempt from requirements established by or pursuant to this Act any hazardous substance or container if it finds that adequate requirements satisfying the purposes of this Act have been established by or pursuant to any other Act of Congress...

* * *

PROHIBITED ACTS

XVII SEC. 4.

The following acts and the causing thereof are hereby prohibited:

(a) Introduction or delivery for introduction into interstate commerce of any misbranded hazardous substance or banned hazardous substance.

(b) Alteration of a label or any other action which results in a hazardous substance being a misbranded or banned hazardous substance.

(c) Receipt in interstate commerce of any misbranded hazardous substance or banned hazardous substance or delivery or proffered delivery thereof for pay or otherwise.

(d) Giving a false guarantee or undertaking [explained in section 5(b)(2) below] except by a person who relied upon a preceding guarantee or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the hazardous substance.

(e) The failure to permit entry or inspection as authorized by section 11(b) or to permit access to and copying of any record as authorized by section 12.

(f) Receipt, delivery or introduction into interstate commerce, of a hazardous substance in a reused food, drug, or cosmetic container or in a new container which is identifiable as a food, drug, or cosmetic container by its labeling or by other identification...

XIV (h) The use by any person to his own advantage, or revealing other than to the Commission or its officers or employees, or to the courts of any information acquired under authority of section 11 concerning any method or process which, as a trade secret, is entitled to protection.

PENALTIES

SEC. 5...

VI (b) No person shall be subject to penalties (1) for having violated section 4(c), if the receipt, delivery, or proffered delivery of the hazardous substance was made in good faith, unless he refuses to furnish the name and address of the person from whom he purchased or received such hazardous substance, and copies of all documents pertaining to the delivery of the hazardous substance to him; or (2) for having violated section 4(a), if he establishes a guarantee or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the hazardous substance, to the effect that the hazardous substance is not a misbranded hazardous substance or a banned hazardous substance; or (3) for having violated subsection 4(a) or 4(c) in respect of any hazardous substance shipped or delivered for shipment for export to any foreign country, in a package marked for export on the outside of the shipping container and labeled in accordance with the specifications of the foreign purchaser and in accordance with the laws of the foreign country and actually exported.

* - *

REGULATIONS

SEC. 10.

VII (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Commission.

XVII (b) The Secretary of the Treasury and the Commission shall jointly prescribe regulations for the efficient enforcement of the provisions of section 14 [Imports], except as otherwise provided therein...

III

EXAMINATIONS AND INVESTIGATIONS

VIII SEC. 11.

(a) The Commission is authorized to conduct examinations, inspections, and investigations for the purposes of this Act through officers and employees of the Commission or through any health officer or employee of any State, territory, or political subdivision thereof, duly designated.

(b) For purposes of enforcement of this Act, officers designated by the Commission, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which hazardous substances are manufactured, processed, packed, or held for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such hazardous substances in interstate commerce; (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle, and all pertinent equipment, finished and unfinished materials, and labeling therein; and (3) to obtain samples of such materials, packages, or labeling. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection.

(c) If the officer obtains any sample, prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained. If an analysis is made of such sample, a copy of the results shall be furnished to the owner, operator, or agent in charge.

RECORDS OF INTERSTATE SHIPMENT

VIII SEC. 12.

For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving hazardous substances in interstate commerce or holding such hazardous substances shall, upon the request of an officer designated by the Commission, permit access to and copying of all records showing the movement in interstate commerce of any such hazardous substance, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any record requested when the request is accompanied by a statement in writing specifying the nature or kind of hazardous substance to which the request relates: Provided, that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom

obtained: Provided further, that carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of hazardous substances in the usual course of business as carriers.

PUBLICITY

XIV SEC. 13...

II (b) The Commission may disseminate information regarding hazardous substances in situations involving, in the opinion of the Commission, imminent danger to health. Nothing in this section shall be construed to prohibit the Commission from collecting, reporting, and illustrating the results of its investigations.

IMPORTS

XVII SEC. 14.

VIII (a) The Secretary of the Treasury shall deliver to the Commission upon request, samples of hazardous substances which are being imported or offered for import into the United States, giving notice to the owner or consignee, who may appear before the Commission and have the right to introduce testimony. If it appears that such hazardous substance is a misbranded hazardous substance or banned hazardous substance or in violation of section 4(f) [packaged in reused or new food, drug or cosmetic containers], then such hazardous substance shall be refused admission. The Secretary of the Treasury shall cause the destruction of any such hazardous substance refused admission unless the substance is exported within ninety days of the date of notice of such refusal or within such additional time as may be permitted by the Secretary of the Treasury.

* * *

EFFECT UPON FEDERAL AND STATE LAW

XVII SEC. 18...

III (b) (1) (A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) designated to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b).

(2) [The Federal Government and State Government may agree to different standards or requirements for a special purpose.]

(3) [The Commission may allow a requirement which provides a significantly higher degree of protection, but which will not unduly burden interstate commerce.]

(4) [labeling of fireworks] ...

* * *

[NOTE: The authorities and responsibilities of the Secretary of Health, Education, and Welfare, the Secretary of Commerce and the Federal Trade Commission under the Flammable Fabrics Act were transferred by section 30 of the Consumer Product Safety Act (CPSA) to the Consumer Product Safety Commission (CPSC). "Commission" hereinafter refers to the CPSC.]

The discretionary powers of the Commission under this act to gather data which might be useful to toxic substances regulation are minimal. However, the general authorities of subsections 5(c) and 5(d) may be currently used or potentially useful for gathering data on the use of certain chemicals in the textile industry.]

PUBLIC LAW 90-189 -- December 14, 1967

as amended by

PUBLIC LAW 92-284 -- May 11, 1976

"FLAMMABLE FABRICS ACT"

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REGULATION OF FLAMMABLE FABRICS

SEC. 4...

XVII

(b) Each [flammability] standard or regulation shall be based on findings that such standard, regulation or amendment is needed to protect the public against unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage; is reasonable, technologically practicable, and appropriate; is limited to fabrics, related materials, or products which have been determined to present such unreasonable risks; and shall be stated in objective terms...

IX
VII

(c) The Commission may obtain from any person, by regulation or subpoena, such information in the form of testimony, books, records, or other writings as is pertinent to the findings or determinations which he is required or authorized to make pursuant to this Act. All information reported to or otherwise obtained by the Commission or its representative pursuant to this subsection which contains or relates to a trade secret or other matter referred to in section 1905 of Title 18, United States Code, shall be considered confidential for the purpose of that section, except that such information may be disclosed to other officers or employees concerned with carrying out this Act or when relevant in any proceeding under this Act. Nothing in this section shall authorize withholding of information by the Commission from the duly authorized committees of the Congress...

XIV

ADMINISTRATION AND ENFORCEMENT

SEC. 5...

VII (c) The Commission is directed to prescribe rules and regulations, including provisions for maintenance of records relating to fabrics, related materials, and products, necessary for administration and enforcement of this Act...

I (d) The Commission is authorized to —

(1) cause inspections, analyses, tests, and examinations to be made of any product, fabric, or related material which it has reason to believe falls within the prohibitions of this Act; and

III (2) cooperate on matters related to the purpose of this Act with any department or agency of the Government; with any State... or with any person.

* * *

NATIONAL ADVISORY COMMITTEE FOR THE FLAMMABLE
FABRICS ACT

IV SEC. 17...

(a) The Secretary of Commerce shall appoint a National Advisory Committee for the Flammable Fabrics Act, composed of not less than nine members, fairly representative of manufacturers, distributors, and the consuming public. The members of the Committee who are appointed to represent manufacturers shall include representatives from (1) the natural fiber producing industry, (2) the manmade fiber producing industry, and (3) manufacturers of fabrics, related materials, apparel, or interior furnishings. Each member appointed by the Secretary shall hold office for not more than two years, except that any member may be reappointed.

(c) The Secretary shall consult with the National Advisory Committee before prescribing flammability standards or other regulations established under this Act.

PUBLIC LAW 91-601 — December 30, 1970

"POISON PREVENTION PACKAGING ACT"

[Note: Section 30 of the Consumer Product Safety Act transferred the functions of the Secretary of Health, Education and Welfare under the Poison Prevention Packaging Act to the Consumer Product Safety Commission.]

* * *

IV SEC. 6...

(a) For the purpose of assisting in carrying out the purposes of this Act, the Secretary shall appoint a technical advisory committee, designating a member thereof to be chairman, composed of not more than eighteen members who are representative of (1) the Department of Health, Education, and Welfare, (2) the Department of Commerce, (3) manufacturers of household substances subject to this Act, (4) scientists with expertise related to this Act and licensed practitioners in the medical field, (5) consumers, and (6) manufacturers of packages and closures for household substances. The Secretary shall consult with the technical advisory committee in making findings and in establishing standards pursuant to this Act...

* * *

PUBLIC LAW 93-633 -- January 3, 1975

TITLE I -- HAZARDOUS MATERIALS

SHORT TITLE

SEC. 101.

XVII This title may be cited as the "Hazardous Materials Transportation Act".

SEC. 102.

It is declared to be the policy of Congress in this title to improve the regulatory and enforcement authority of the Secretary of Transportation to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce.

* * *

DEFINITIONS

SEC. 103.

As used in this title:...

XVI (2) "Hazardous material" means a substance or material in a quantity and form which may pose an unreasonable risk to health and safety or property when transported in commerce;

XVI (3) "Secretary" means the Secretary of Transportation;...

DESIGNATION OF HAZARDOUS MATERIALS

XVII SEC. 104.

Upon a finding by the Secretary, in his discretion, that the transportation of a particular quantity and form of a material in commerce may pose an unreasonable risk to health and safety or property, he shall designate such quantity and form of material or group or class of such materials as a hazardous material. The materials so designated may include, but are not limited to, explosives, radioactive materials, etiologic agents, flammable liquids or solids, combustible liquids or solids, poisons, oxidizing or corrosive materials, and compressed gases.

SEC. 105.

- (a) GENERAL. -- The Secretary may issue regulations for the safe transportation in commerce of hazardous materials. Such regulations shall be applicable to any person who transports, or causes to be transported or shipped, a hazardous material, or who manufactures, fabricates, marks, maintains, reconditions, repairs, or tests a package or container which is represented, marked, certified, or sold by such person for use in transportation of hazardous materials. Such regulations may govern any safety aspect of the transportation of hazardous materials which the Secretary deems appropriate, including the packing, repacking, handling, labeling, marking, placarding, and routing (other than with respect to pipelines) of hazardous materials, and the manufacture, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold by such person for use in the transportation of hazardous materials.
- XV
- (b) COOPERATION. -- ... the Secretary shall consult and cooperate with representatives of the Interstate Commerce Commission and shall consider any relevant suggestions made by such Commission, before issuing any regulation with respect to the routing of hazardous materials.
- III
- (c) REPRESENTATION. -- No person shall, by marking or otherwise, represent that a container or package for the transportation of hazardous materials is safe, certified, or in compliance with the requirements of this Act, unless it meets the requirements of all applicable regulations issued under this Act.
- XVII

HANDLING OF HAZARDOUS MATERIALS

SEC. 106.

- (a) CRITERIA. -- The Secretary is authorized to establish criteria for handling hazardous materials. Such criteria may include, but need not be limited to, a minimum number of personnel; a minimum level of training and qualification for such personnel; type and frequency of inspection; equipment to be used for detection, warning, and control of risks posed by such materials; specifications regarding the use of equipment and facilities used in the handling and transportation of such materials; and a system of monitoring safety assurance procedures for the transportation of such materials.
- V
- (b) REGISTRATION. -- Each person who transports hazardous materials or who manufactures, fabricates, marks, maintains, reconditions, repairs, or tests packages or containers which are represented, marked, certified, or sold for use in the transportation of hazardous materials may be required to prepare and submit a registration statement not more
- X
- XII

often than once every two years which shall include, but need not be limited to, such person's name; principal place of business; the location of each activity handling such hazardous materials; a complete list of all hazardous materials handled; and an averment that such person is in compliance with all applicable criteria established under subsection (a) above. The Secretary shall by regulation prescribe the form of any such statement and the information required to be included. The Secretary shall make any registration statement filed pursuant to this subsection available for inspection by any person without charge, except that nothing in this sentence shall be deemed to require the release of any information described by subsection (b) of section 552 of title 5, United States Code, or which is otherwise protected by law from disclosure to the public.

XIV

X (c) REQUIREMENT. -- No person required to file a registration statement under subsection (b) above may transport or ship extremely hazardous materials [not separately defined, ed.] or manufacture, fabricate, mark, maintain, recondition, repair, or test packages or containers for use in the transportation of extremely hazardous materials, unless he has on file a registration statement.

EXEMPTIONS

X SEC. 107.

(a) GENERAL. -- The Secretary is authorized to issue or renew, to any person subject to the requirements of this title, an exemption from such provisions, and from regulations issued under section 105 above, if such person transports or ships hazardous materials at a level of safety which is equal to or exceeds that level of safety which would be required without such exemption, or which would be consistent with the public interest and the policy of this title in the event there is no existing level of safety established. The maximum period of an exemption issued or renewed shall not exceed 2 years, but any such exemptions may be renewed upon application to the Secretary. Each person applying for an exemption or renewal shall provide a safety analysis as prescribed by the Secretary to justify the grant of such exemption. Notice of an application for issuance or renewal of an exemption shall be published in the Federal Register. The Secretary shall afford access to any such safety analysis and an opportunity for public comment on any such application, except that nothing in this sentence shall be deemed to require the release of any information described by subsection (b) of section 552 of title 5, United States Code, or which is otherwise protected by law from disclosure to the public...

XIV

(d) LIMITATION ON AUTHORITY. -- Except when the Secretary determines that an emergency exists, exemptions or renewals granted pursuant to this section shall be the only means by which a person may be exempted from or relieved of under this title.

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POWERS AND DUTIES OF THE SECRETARY

SEC. 109.

II (a) GENERAL. -- The Secretary is authorized to conduct necessary investigations, make reports, issue subpoenas, conduct hearings, require IX the production of relevant documents, records, and property, take depositions, and conduct, directly or indirectly, research, development, demonstration, and training activities. The Secretary is further authorized, after notice and an opportunity for a hearing, to issue orders directing compliance with this title or regulations issued under this title; the district courts of the United States shall have jurisdiction, upon petition by the Attorney General, to enforce such orders by appropriate means.

VII (b) RECORDS. -- Each person subject to requirements under this XIII title shall establish and maintain such records, make such reports, and provide such information as the Secretary shall by order or regulation prescribe, and shall submit such reports and shall make such records and information available as the Secretary may request.

VIII (c) INSPECTION. -- The Secretary may authorize any officer to enter upon, inspect, and examine, at reasonable times and in a reasonable manner, the records and properties of persons to the extent such records and properties relate to --

(1) the manufacture, fabrication, marking, maintenance, reconditioning, repair, testing, or distribution of packages or containers for use by any person in the transportation of hazardous materials in commerce; or

(2) the transportation or shipment by any person of hazardous materials in commerce.

II (d) FACILITIES AND DUTIES. -- The Secretary shall --

(1) establish and maintain facilities and technical staff sufficient to provide, within the Federal government, the capability of evaluating risks connected with the transportation of hazardous materials and materials alleged to be hazardous;

(2) establish and maintain a central reporting system and data center so as to be able to provide the law enforcement and fire fighting personnel of communities, and other interested persons and government officers, with technical and other information and advice for meeting emergencies connected with the transportation of hazardous materials; and

(3) conduct a continuing review of all aspects of the transportation of hazardous materials in order to determine and to be able to recommend appropriate steps to assure the safe transportation of hazardous materials.

II (e) ANNUAL REPORT. -- The Secretary shall prepare and submit to the President for transmittal to the Congress on or before May 1 of each year a comprehensive report on the transportation of hazardous materials during the preceding calendar year. Such report shall include, but need not be limited to --

(1) a thorough statistical compilation of any accidents and casualties involving the transportation of hazardous materials;...

* * *

TITLE III -- INDEPENDENT SAFETY BOARD

XVII SEC. 301.

This title may be cited as the "Independent Safety Board Act of 1974".

* * *

NATIONAL TRANSPORTATION SAFETY BOARD

XVII SEC. 303.

(a) ESTABLISHMENT. -- The National Transportation Safety Board, previously established within the Department of Transportation, shall be an independent agency of the United States, in accordance with this section, on and after April 1, 1975.

(b) ORGANIZATION. --

(1) The Board shall consist of five members, including a Chairman. Members of the Board shall be appointed by the President, by and with the advice and consent of the Senate...

GENERAL PROVISIONS

SEC. 304.

(a) DUTIES OF BOARD. -- The Board shall --...

II (4) initiate and conduct special studies and special investigations on matters pertaining to safety in transportation including human injury avoidance;...

II (8) evaluate the adequacy of safeguards and procedures concerning the transportation of hazardous materials and the performance of other Government agencies charged with assuring the safe transportation of such materials;...

(b) POWERS OF BOARD. --

IX (1) The Board, or any designated officer of the Board, may, for the purpose of carrying out this title, hold such hearings, sit and act at such times and places, administer such oaths, and require by subpoena or otherwise the attendance and testimony of such witnesses and the production of such evidence as the Board or such officer deems advisable. Subpoenas shall be issued under the signature of the Chairman, or his delegate...

VIII (2) Any employee of the Board, upon presenting appropriate credentials and a written notice of inspection authority, is authorized to enter any property where a transportation accident has occurred or wreckage from any such accident is located and do all things necessary for a proper investigation. The employee may inspect, at reasonable times, records, files, papers, processes, controls, and facilities relevant to the investigation of such accident. Each inspection shall be commenced and completed with reasonable promptness and the results of such inspection made available [to whom is not specified]...

XIII (9) The Board, or an employee designated by the Chairman, may conduct an inquiry to secure data with respect to any matter pertinent to transportation safety, upon publication of notice of such inquiry in the Federal Register; and by special or general order, may require Federal, State and local government agencies and persons engaged in the transportation of people or property in commerce to submit written reports and answers to such requests and questions as are propounded with respect to any matter pertinent to any function of the Board. Such reports and answers shall be submitted to the Board or to such employee within a reasonable period of time and in the form the Board determines. Copies shall be made available for inspection by the public.

* * *

PUBLIC ACCESS TO INFORMATION

XIV SEC. 306.

(a) GENERAL. -- Copies of any communication, document, investigation, or other report, or information received or sent by the Board

shall be made available to the public upon identifiable request, and at reasonable cost, unless such information may not be publicly released pursuant to subsection (b) below. Nothing contained in this section shall be deemed to require the release of any information described by subsection (b) of section 552 of title 5, United States Code, or which is otherwise protected by law from disclosure to the public.

(b) EXCEPTION. -- The Board shall not disclose information obtained under this title which concerns a trade secret referred to in section 1905 of title 18, United States Code, except that such information may be disclosed in a manner designated to preserve confidentiality --

(1) upon request, to other Federal Government departments and agencies for official use;... and

(4) to the public in order to protect health and safety, but only after notice to any person to whom the information pertains and an opportunity to comment in writing, or orally in closed session, on such proposed disclosure if the delay for comment would not be detrimental to health and safety.

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PUBLIC LAW 458 -- October 16, 1970

"AN ACT"

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TITLE II -- RAILROAD SAFETY

SEC. 201. SHORT TITLE.

This title may be cited as the "Federal Railroad Safety Act of 1970".

SEC. 202. RAIL SAFETY REGULATIONS.

- II (a) The Secretary of Transportation shall prescribe as necessary, appropriate rules, regulations, orders, and standards for all areas of railroad safety supplementing provisions of law and regulations in effect on the date of enactment of this title, and conduct, as necessary, research, development, testing, evaluation, and training for all areas of railroad safety...

* * *

SEC. 206. STATE PARTICIPATION.

- X (a) A State may participate in carrying out investigative and surveillance activities in connection with any rule, regulation, order, or standard prescribed by the Secretary if the appropriate State agency submits to the Secretary an annual certification that such State agency —

(1) has regulatory jurisdiction over the safety practices applicable to railroad facilities, equipment, rolling stock, and operations within the State concerned;

(2) has been furnished a copy of each Federal safety rule, regulation, order, and standard, applicable to any such railroad facility, equipment, rolling stock, or operation, established under this title as of the date of the certification;

- V (3) is conducting the investigative and surveillance activities prescribed by the Secretary as necessary for the enforcement by him of each rule, regulation, order, and standard referred to in paragraph (2) above, as interpreted by the Secretary.

XII (b) Each annual certification shall include a report, in such form as the Secretary may by regulation provide, showing -- ...

(2) all accidents or incidents reported by each railroad during the preceding twelve months involving personal injury requiring hospitalization, fatality, or property damage exceeding \$750 or such other higher amount as the Secretary may prescribe, together with a summary of the State agency's investigation as to the cause and circumstances surrounding each such accident or incident;

VI (3) the record maintenance, reporting, and inspection practices conducted by the State agency to aid the Secretary in his enforcement of rules, regulations, orders, and standards prescribed by him under section 202(a) of this title, including a detail of the number of inspections made by the State agency during the preceding twelve months; and

VII (4) such other information as the Secretary may require...

V (e) The Secretary is authorized to conduct such monitoring of State investigative and surveillance practices and such other inspections and investigations as may be necessary to aid in the enforcement of the provisions of this title.

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SEC. 208. GENERAL POWERS.

(a) In carrying out his functions under this title, the Secretary is authorized to perform such acts including but not limited to, conducting investigations, making reports, issuing subpoenas, requiring production of documents, taking depositions, prescribing record-keeping and reporting requirements, carrying out and contracting for research, development, testing, evaluation, and training, and delegating to any public bodies or qualified persons, functions respecting examination, inspection, and testing of railroad facilities, equipment, rolling stock, operations, or persons, as he deems necessary to carry out the provisions of this title. The Secretary is further authorized to issue orders directing compliance with this Act or with any railroad safety rule, regulation, or order or standard issued under this Act; the district courts of the United States shall have jurisdiction, upon petition of the Attorney General, to enforce such orders by appropriate means.

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- VIII (c) To carry out the Secretary's responsibilities under this title, agents of the Secretary are authorized to enter upon, inspect, and examine rail facilities, equipment, rolling stock, operations, and pertinent records at reasonable times and in a reasonable manner. Such agents shall display proper credentials when requested.

TITLE III -- HAZARDOUS MATERIALS CONTROL

- XVII SEC. 301. SHORT TITLE.

This title may be cited as the "Hazardous Materials Transportation Control Act of 1970".

[Note: The "Hazardous Materials Transportation Control Act of 1970" was repealed by PUBLIC LAW 93-633 -- January 3, 1975 included elsewhere in this compendium.]